Ca' Foscari
University
of Venice

Master's degree programme in

Language and Management to China

Final Thesis

A comprehensive analysis of the medical device market and the role of the People's Republic of China in the industry

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Academic Year
2023 / 2024

Index

List of tables 5

List of figures 6

前言 7

Introduction 11

Chapter 1: Medical device market, environmental analysis 13

1.1 Global industry overview 13

1.2 Regulatory frameworks and their role in the medical device market 15

1.2.1 USA regulatory framework 16

1.2.2 Europe regulatory framework 17

1.2.3 China regulatory framework 17

1.3 The benefit of progressive standardization of regulatory framework 18

1.4 Medical device market drivers 20

1.5 International trade of medical device, preliminary environmental analysis 23

Chapter 2: Medical device market, review of quantitative analysis 26

2.1 Methodology 26

2.2 Global medical device market size 27

2.3 Product-based market segmentation of medical device 29

2.4 International trade of medical device, review of quantitative analysis 33

2.4.1 Most influential countries in the international medical device market trade 39

2.4.2 China role and contribution in medical device international trade 40

2.5 Areal insight USA, Europe, APAC 44

2.5.1 USA medical device market 44

2.5.2 Europe medical device market 45

2.5.3 APAC medical device market 47

Chapter 3: Chinese Government's policies for the domestic medical device market 56

3.1 China's healthcare system 56

3.2 Breakdown of medical device industrial clusters in China 58

3.3 Overview of the main Chinese company involved in the industry 61

3.4 Overview of the Chinese government's policies for the domestic medical device market 63

3.4.1 Made in China 2025 64

3.4.2 Healthy China 2030 65

3.4.3 Medical technology in the 14th five-year plan (2021-2025) 66

3.4.4 Centralised state procurement (CSP) and volume-base procurement (VBP) 66

3.4.5 CSP and VBP latest results 68

3.4.6 CSP and VBP consequences 69

3.5 Foreign answer: Trade protection tools and protective measures against China 71

3.6 Chinese domestic answer: Going global the path of chuhai (出海) 72

Chapter 4: Comparative literature analysis 75

4.1 Structure and methodology of the comparative analysis 75

4.2 Topic 1: Post-pandemic global health situation 76

4.2.1 Post-pandemic consequences 76

4.2.2 Global Health Diplomacy 77

4.3 Topic 2: Innovation in medical devices and future trends 79

4.3.1 New medical device technologies 80

4.3.2 AI impact on the industry and China's contribution 82

4.4 Topic 3: How the ageing of the world population influences the medical device market 84

4.4.1 Global and China ageing population overview 84

4.4.2 Ageing population impact on the economy, environment and society 86

4.4.3 Red Herring Hypothesis 88

4.4.4 Healthy ageing and person-centred medical devices 88

4.5 Topic 4: Environmental sustainability solutions in the medical device industry 89

4.5.1 Global carbon footprint of the healthcare sector 90

4.5.2 Medical waste disposal challenges..... 92

4.5.3 Sustainable solution for the medical device industry..... 93

4.5.4 Policy recommendations for the sustainability of the national healthcare sector..... 95

4.6 Comparative literature analysis result evaluation 96

5. Conclusions.....99

References 102

Bibliography.....102

Website 111

List of tables

Table 1: Top 10 export countries (on the left), Top 10 import countries (on the right) from 2001 to 2020.....35

Table 2: Nodes measure of global medical device trade networks 38

Table 3: Most influential countries in the international medical device market trade.....39

Table 4: Overview measures of China's contribution to the medical device global trade network 40

Table 5: China's major export destinations over time (2001-2020).....42

Table 6: Overview of the main Chinese company involved in the industry.....61

Table 7: Centralised state procurement evolution timeline. 67

Table 8: Literature evaluating post-pandemic global health situation. 76

Table 9: Literature evaluating innovation in medical devices and future trends 79

Table 10: Literature evaluating how ageing of the world population influences the medical device market 84

Table 11: Literature evaluating environmental sustainability solutions in the medical device industry 89

Table 12: Snapshots of China (on the left) and Europe (on the right) emissions 91

List of figures

Figure 1: Medical device market access procedure 15
Figure 2: Global map of medical device complexity of each country 22
Figure 3: Forecast of the global medical device market value 28
Figure 4: Top 7 Market medical device revenue & forecast for 2030 and medical device market shares by region 2023 28
Figure 5: Global market share and sales growth by medical device segment (2021-2028) 30
Figure 6: Overview of the Global Medical Device Trade Network from 1990 to 2020 33
Figure 7: Medical device international trade space 37
Figure 8: Chinese influence propagation model 43
Figure 9: Medical device market size compared by region 48
Figure 10: Forecast of China's medical device market and product categories size (2016-2024) 52
Figure 11: Comparison between global and Chinese patent applications (1999-2014) 54
Figure 12: Chinese Public Health structure 57
Figure 13: China's MedTech support as share of revenue (%) compared to OECD countries 63
Figure 14: Global Health Diplomacy key area of implementation. 78
Figure 15: USA and China research focuses 81
Figure 16: Life expectancy at birth, 1950–2050 85
Figure 17: Healthcare expenditures per capita (left) and per gross domestic product (right) 86
Figure 18: Greenhouse gas emission by region 90
Figure 19: Emissions reduction potential for China's health sector from several combined policy solutions. 96

前言

在2023-2024学年，Ca Foscari University 赋予了我宝贵的海外项目学习机会。为期一年的学习交流使我能够在位于中国江苏省苏州市的知名院校——西交利物浦大学度过两个学期。我得以在这个被誉为“亚洲世纪”中心的国家，攻读国际商业与市场营销课程，实现了我一生的梦想。我在中国学习期间所表现出的决心和毅力，使我获得了一家总部位于苏州工业园区（SIP），特别是在苏州 Bio Bay Area 运营的中国医疗器械领域咨询公司市场营销助理的实习机会。该地区聚集了江苏省 经营医疗器械和医药产品行业的最大数量的公司，且构建了相应的网络。这家公司名为MDCE，自2019年成立以来便享誉全国，由公司总经理邓晓宇创立，且与我共事。MDCE 因指导一家中国新冠检测生产商将其同类产品首次推向美国市场，而成为国家发展史上的一个重要里程碑。我在营销部门工作，与业务发展部门的同事密切合作，通过对竞争对手的分析、 国外市场（主要为亚太地区和欧洲）的分析以及客户关系管理（CRM），加深了对中国医疗器械市场动态的了解。我得知，该行业正经历着强烈的全球化驱动，这一趋势在行业的利益相关者中均有体现。我参加了包括中国最大的医疗器械国际化展览会——2024苏州医博会（China Medical Fair Suzhou 2024）在内的多个贸易展会，得以与在该领域拥有数十年经验的中国专业人士直接交流，并从他们那里获得了宝贵的信息和 证言。正是这段经历促使我决定将医疗器械市场的综合分析作为我的毕业论文，由我的好奇驱动来证明我的印象和经历是否在学术文献中有所反映，并希望继续研究这个在未来必然发挥重要作用的市场。

分析的出发点是我观察到在进行市场分析并选择考虑中国的参数时，医疗器械行业往往被大众消费品、 汽车或科技等更传统的市场所掩盖，因为在上述市场中，中国在供应链的各个阶段都发挥着主导作用，而在医疗行业，多年来中国一直局限于“复制生产”的模式。然而，这与我在中国亲身经历的情况截然不同，在那里我看到并感知到一个高度活跃、创新的环境，在许多方面都准备好巩固在亚洲区域市场和世界市场的领先地位，以便达到其他行业已经达到的地位。

一般来说，医疗器械市场一直比其他市场反响平平，这是因为长期以来它们在支持国家 医疗保健体系方面所发挥的根本作用被认为是有保障的，尤其是在欧洲和美国等高度发达和工业化的国家。但2020年，当震惊了世界人口的新冠肺炎疫情在中国武汉爆发，证明现代流行病仍然有能力使最大的国家医疗保健系统陷入瘫痪时，这一局面突然被颠覆。这场健康危机引起了各国政府和世界人口的关注，唤醒了人们对全球健康、国际卫生合作以及公民的个人健康和确保平等获得治疗权利等 概念的关注，所有这些都将聚光灯投向了医疗器械市场。

自2019年以来，学术文献产生了大量关于医疗器械市场当前状况和未来发展的研究。这是一个中国在其中所扮演的角色尚未明确，或者至少不为公众所知的市场。在疫情期间，曾发生过对中国人的可耻的种族主义事件，然而，绝大多数人不知道的是，中国及其国内市场在抗击病毒的过程中，通过提供大量的低 技术含量的医疗器械，如口罩、检测试剂和患者监护仪等，为支持各国国家医疗保健系统发挥了关键作用。

因此，鉴于此，本文的目的是回答三个问题。这些问题回答了全球医疗器械市场的现状、其贸易的经济规模以及绘制出区分该行业的其中主要特征的指南之一。为了深入介绍中国和国内市场、支配其的规则及其全球野心，以及鉴于该行业的复杂性，我 试图通过进行文献比较分析，以整体的方式来处理这个问题，即四个不可避免地影响该行业的全球趋势：后疫情时代的医疗保健管理、全球人口老龄化、具有影响力的技术（例如人工智能或物联网）的未来技术发展以及该行业的气候影响和可持续性。

该行业的蓝图是一个高度管制的 B2B 网络，其中最常见的最终用户是国家医疗保健系统（NHS）提供商和公立或私立医疗机构，尽管如此，一部分市场 仍被个人用户所占据。医疗器械（MDs）代表了一大类广泛的医疗保健产品，每种产品在设计、应用和预期用途上都是独一无二的。目前，市场包含约50,000个不同种类的1,700种设备。世界卫生组织将医疗器械定义为专为医疗目的而创建的所有仪器、装置、植入物或设备——无论是用于诊断、预防、监测或治疗健康状况。这一广泛的分类包括传统医疗器械（包括假肢、手术 器械、人造器官和生命支持设备）以及体外诊断（IVD）设备。该行业受到高度监管。法规由所谓的通知机构修订，并且每个国家都有不同的方面。事实上，监管框架之间的差异是该行业最大的障碍之一。但是，涉及政府和国际机构的几项趋势正在进行中，以标准化各种监管框架。在这一切中，中国通过应用监管依赖，在亚太地区发挥了关键的 领导作用。

2024年，医疗器械行业展现了其实力和韧性，市场总值达到5080亿美元。该行业不仅恢复了活力，而且从长远来看蓬勃发展，专家预测其将以5.68%的复合年均增长率持续增长。市场预测显示，到2029年，全球产出将达到 6697亿美元。主要是医院和诊所的医疗机构，产生了约88.5%的总收入，个人最终用户则几乎占据了剩余的全部销售额。

实证分析揭示了全球生产中存在显著的地理不平衡，该行业严重依赖出口。国际市场结构以具有强大影响力的出口大国为特征，这些国家对邻近地区 产生相当大的影响。美国、一些欧洲国家以及近期的中国，一直在稳步增强其在市场中的核心地位，削弱了历史上重要的中介国家在传统上促进全球贸易网络内部联系的作用。

中国在全球医疗器械领域的影响力以三种截然不同的方式体现：作为主要的出口国、作为寻求复制其十年内行业惊人增长的发展中经济体的理想典范，以及促进全球市场准入，作为在亚太地区开发和协调监管框架的关键 参与者。·

尽管实施了旨在在先进医疗技术领域建立国内和国际领导地位的政策，但中国仍主要出口低端医疗器械。

在全球医疗器械行业迅速演变的背景下，中国正经历从“复制生产”到“自主创新”的关键转型。虽然中国历来侧重于低端医疗器械的生产和出口，但最近的国内政策、技术进步和全球市场战略正推动其向高端领域转变。

这一发展主要归因于中国政府实施的政策，包括“健康中国2030”，以及2021-2025年五年计划中重新强调医疗器械开发中的先进技术。这些干预措施的范围更广，并没有将医疗器械置于其蓝图的中心。相比之下，2019年最新采用的集中国家采购与基于采购量的采购相结合，将医疗器械置于中心地位，事实上，上述“内卷”在很大程度上是实施这项政策的结果。该政策通过区域、省级和市级招标来运作。国内外制造商均可参与投标。因此，中标者会为选定的产品类别和特定的地理区域规定一份合同。该合同允许中标生产商在每个地区针对给定产品进行批量采购制度下的运营，因此，医院和诊所将被迫从这家中标公司获得该医疗器械的供应。批量采购导致医疗器械生产成本和市场价格逐渐降低，使更多 公司能够获得市场份额，并加剧了内部竞争。除了经济利益外，医疗器械行业现在经历了现代中国的一个普遍趋势：集中国家采购加剧了所谓的“内卷”现象。这个词描述了市场因竞争者过多而趋于饱和的内卷。因此，中国企业已坚定地决定向国外扩张，并遵循“出海”的道路。

与此同时，国际医疗器械市场继续受到监管框架分散、人口老龄化、技术突破和可持续性担忧等挑战的影响。 这些因素不仅定义了当前的行业格局，而且决定了其未来的发展轨迹。

本研究的核心目标是从全球视角分析医疗器械行业的当前状况、新兴趋势和关键挑战，特别关注中国的崛起及其不断扩大的全球影响力。通过研究行业数据、监管框架、技术进步和市场结构演变，本研究旨在为理解该行业的未来方向提供一个系统框架。

医疗器械行业不仅对医疗保健 系统的可持续性至关重要，而且与国家战略、技术竞争力和全球公共卫生安全紧密相连。因此，对该行业的研究对政策制定者、企业和投资者而言，既具有学术意义，又具有实用价值。中国能否在全球高端医疗器械市场中占据主导地位，将取决于其技术突破、适应国际市场的能力以及加深参与全球监管合作。

在此背景下，本研究旨在提供对医疗器械行业当前格局和未来发展的 综合分析，同时激发对其长期演变的进一步讨论。随着市场的持续转型，对中国角色和更广泛的全球医疗器械行业的持续研究，对于理解全球医疗保健的未来结构至关重要

Introduction

The medical device market is a crucial healthcare industry sector that is not ruled by classic economic principles since it presents some peculiarities. Due to its impact on public and individual health, the market is governed by a complex regulatory framework that varies from country to country and influences each phase of the medical device life cycle, from design to market placement. Because of the sensitivity of their role in society, medical devices depend on technological innovations and are subject to macro-demographic and social trends or ethical implications.

The questions that moved the research are the following:

Q1: What are the main characteristics of the medical device market in its current state?

Q2: What is China's role in the industry?

Q3: Is the international and Chinese domestic literature aligned or misaligned on various aspects of the topic?

Therefore, this paper aims to provide a comprehensive overview of the medical device market and industry, examining its heterogeneous nature and focusing on China's role and contributions. It explores the global economic impact of the medical device market, the key players in the industry, and the interaction of medical devices with other major modern trends. Additionally, the paper analyzes China's perspective, the actions of the Chinese government in the domestic medical device market, and the future of China in the global industry. It also considers the external perception of China in this context. The study applies a mixed approach, combining qualitative and review of quantitative analysis to describe the industry environment and economic performances.

The first chapter of the thesis is a qualitative environmental analysis and the general aspects of the medical device market. Firstly, it covers the standard categorization of the goods and the principle behind them. The process that leads to market access of the medical device is also briefly presented. In addition, the section will delve into the general guidelines of the regulatory framework, with three specific sections reserved to present a comparative perspective of the regulatory environment and related notify bodies of the three main markets in the industry: US, Europe and China. The differences between the three markets represent a bridge to expand the analysis on the consequences and role of such an invasive regulatory framework and the latest international trends of normalization of the system. In the last two paragraphs of the first chapter are discussed industry market drivers and the international medical device market environment.

The second chapter of the paper is a review of a quantitative description of the market, evaluating relevant data from secondary sources. It aims to give a precise and punctual economic picture of the

medical device market's current status and global output and its major players. The section is divided into a static and dynamic description and delves from a general perspective into particular areal insight, with dedicated paragraphs to the US, Europe and APAC (Asia Pacific region). The dynamic approach was necessary to describe the influence relationship between the various nations involved in the trade network, with particular attention to the role of China and the path of its influence. The nature of the section is descriptive, and the results presented come from quantitative analysis conducted by third authors.

The third chapter is completely China-centred and adopts a mixed approach of quantitative descriptive and qualitative methods. This solution has been adopted to give a holistic and satisfactory answer about China's quick development of the medical device market and its current role in the industry. Particular emphasis will be placed on the role of the Chinese government and how its policy, directly and indirectly, influences the domestic and international market. This section also tried to capture the domestic trends of medical devices and the future intentions of Chinese industry players, without ignoring the foreign perception of this Chinese evolution in the industry.

The fourth chapter of the study is a comparative literature analysis. This research methodology has been chosen for two main reasons. To begin with, literature analysis has a broader scope to give a general dissertation of the global environment where the medical device market has settled, the major forces which influence it and its future development, moreover the comparative aspect gives the possibility to analyze and compare the Western and Chinese perspectives, which answer perfectly with one of the main objectives of the study.

In the conclusive section, the evaluation and conclusion are presented answering the questions to which the analysis set out to respond.

Overall, each chapter of the thesis is coherently built on the previous one, following a clear path from a general qualitative perspective, it progresses to a quantitative descriptive section and then delves into a specific chapter dedicated to one of the two main macro topics of the dissertation, which is China. In conclusion, a dual-perspective comparative analysis seals up the study after touching every aspect of the industry.

Chapter 1: Medical device market, environmental analysis

1.1 Global industry overview

Medical devices (MDs) are highly differentiated products in design, use, and purpose. To date, 1700 types and around 50,000 units have been registered in the market (Bianchini et al., 2022).

According to the World Health Organization's official definition, a medical device is any instrument, machine, or implant designed and built for medical purposes such as diagnosing, preventing, monitoring, or treating human health diseases. Those cited categories include canonical medical devices (prosthetics, surgical instruments, artificial organs and life-sustaining medical equipment), and In Vitro Diagnostic instruments (IVD). IVDs are solely used for examination, diagnosis, monitoring or compatibility and their category is made up of most medical devices presented in the market. For instance, the well-known COVID-19 antigen tests are IVDs (World Health Organization, 2024). Due to their nature which is not strictly linked to disease treatment, they are considered as extensions of medical devices.

From a global perspective, the medical device industry is a strategic science and technology industry related to national public health and safety. The sector stays at the high end of the value chain and represents the core of the high-tech industrial environment. The industry's blueprint is a highly regulated B2B network where the most common end-users are national healthcare systems (NHS) providers and public or private medical institutions, nonetheless, a portion of the market is occupied by single-person users (Zhang & Rao, 2021).

Medical device technological spectre complexity has a deep breath and functions as the parameter to distinguish and classify the diverse medical device classes. This process is mandatory to ensure a certain standardisation of definition, classification, and nomenclature, however, it is necessary to keep in mind that the medical device classification can vary from country to country (World Health Organization, 2024).

From a market perspective, medical devices can be divided as follows. Starting from the bottom there are low-tech disposables which include personal protection medical devices (PPMDs) and analogical surgical instruments, these goods are for the most part hospital and clinic supplies and most of the time designed for single-time utilization. Scaling up there are medium-end devices with a more complex technology level required to be produced, usually, they can be implantable (orthopaedic prosthetic, pacemaker) or non-implantable (ventilator or infusion pumps) goods. At the top, there are high-end MDs. Those are the most technological items that the industry produces, for instance, AI-powered medical devices or 3D imaging diagnostic instruments. To manufacture this kind of goods high

technological knowledge and skilled labour force are required (Torsekar, 2018).

The classification of medical devices also helps to design a comprehensive regulatory framework to clearly outline the guidelines to ensure the safety, performance and quality requirements. Therefore, from a regulatory perspective, the WHO suggested dividing the industry into 4 classes. The parameter differentiating the class is the risk level measured on patient health outcome after the utilization of the given goods and additional standard factors such as level of invasiveness (duration of use in the body). From this assumption medical device classes are structured in this manner: Class A (Low risk), Class B (Low-moderate risk), Class C (Moderate-high risk), Class D (high risk). The classification for IVD is identical, but there is an additional risk factor: the level of potential harm to public health, attributable to the high infectious hazard to which these disposables are exposed to certain environments (World Health Organization, 2017). The presented framework is the standard and general protocol, the model varies in each country and in the majority of cases the class are only three and named Class I, Class II, and Class III. Further disclosure will be presented for the three major medical device markets (China, USA, and Europe).

The basic principle guiding the production of a medical device is the identification of medical needs. They are connected to the invention and consequently to the implementation of the developed goods (Bianchin et al., 2022). In this context, compliance with the regulatory framework is not the only barrier to ensuring market access of the MD, hence the procedure timeline is longer, takes several steps and is more demanding than any other good **(Fig. 1)**. The process goes through several stages, each step is mandatorily required to be meticulously registered with documents, following good-documentation-practice guidelines, to be traceable, preserve quality and reproduceable at any time if required by the authorities (Amaral et al., 2024). After the first two stages where the intended use of the product is defined, and a prototype is designed based on the regulatory strategy it comes to the actual project development stage. The successful outcome of these stages decides whether or not the new medical device can access the market. During this development phase, the product is subjected to manufacturing and clinical trials or clinical evaluation (Bianchini et al., 2022). According to the WHO, clinical trials are prospective biomedical or behavioral research studies involving human participants, designed to answer specific questions about biomedical or behavioral interventions. These interventions can include new treatments such as drugs, vaccines, medical devices, and various therapeutic approaches, the primary goals of clinical trials are to evaluate the safety, efficacy, and optimal dosages of these interventions (World Health Organization, 2024). These tests are conducted under strict instructions and environment (Good Clinical Practices or GCP) and test results data are collected and evaluated by the regulatory institutions. If everything is approved the medical device can access the market (Amaral et al., 2024).

Figure 1: Medical device market access procedure

Source: Bianchini et al. (2022)

Medical devices need constant updates and checks even after they have entered the market. These checks are carried out in part by the manufacturing company cooperating with the competent authorities and are called post-market clinical follow-up (PMCF). These are especially requested for mid to high-end goods and are conducted with different standardised methods based on the region (Bianchini et al., 2022).

From a business perspective overlaying the value chain of the industry on **Fig.1** is interesting to notice how the most value is added in the first days of the product development when the R&D activities are conducted (around 60%) and the rest is spread in bigger portion during the distribution, marketing, sales and post-sales service, on the other hand during manufacturing assembly is added a low-value amount (Torsekar, 2018). The key performance indicators (KPIs), for example, the value added per employee, value added to cost, and value added to investments, show that the industrial sector may be the most valuable per-employee industry in the world (Bianchini et al., 2022).

1.2 Regulatory frameworks and their role in the medical device market

The main objective of regulatory systems in the medical device market is to ensure the safety of the customer, e.g. the patient. Given the industry's sensitivity, the absolute rigidity and complexity of regulations are understandable on a moral and ethical level. On the other hand, it is undeniable that from a business point of view, they can create major difficulties in accessing the market itself and the possibility of scaling up. Nowadays, medical device companies face increasing market pressures due to rapidly evolving expectations surrounding usability, applications, and software development.

To keep pace, companies must adopt faster product development cycles while maintaining high-quality standards and adhering to industry regulations (Maresova et al., 2020). The regulatory framework is

designed and implemented by national or regional notify bodies which collaborate strictly with the national government. Policies such as regulations, product liability laws, reimbursement systems, and government-funded research play a critical role in driving the development and implementation of new medical devices (Han & Bergmann, 2024). Since innovation is the main driver of the industry, a ludicrous, non-standardised and difficult-to-understand regulatory landscape only creates additional costs and delays. Since the quality of the product remains the priority for manufacturers, multiple verification and validation and strict rigorous assessment present a significant impairment to the market (Maresova et al., 2020).

The main consequence of strict regulations in the industry is “medical device lag”. The medical device lag is essentially the period between the moment when a manufacturer starts the clinical trials and the actual time when the goods are approved to enter the market. This gap creates a delay in time and extra costs that can seriously affect the market revenue. For instance, in the Chinese market, in a generalised situation, the medical device lag is quantified between 2 to 5 years (Zhang & Rao, 2021).

In addition, regulatory background differs in each country and every time manufacturers want to go global must obtain new certifications. These procedures reduce globalization potential even for the biggest company in the industry. Therefore, especially regarding high-end medical devices, this will cause a significant rise in the price and impaired equality of patient access (Amaral et al., 2024). To sum up, the stakeholders who populate the industry are strongly in favour of a simplification of the regulatory system, streamlining to get approval and more importantly global or at least regional harmonization of the procedures and regulations.

1.2.1 USA regulatory framework

The Food and Drug Administration (FDA) is the notify body responsible for the US regulatory framework and is governed by the Federal, Food, and Drug Administration Act (FFDCA). In North America, the goods are divided into three classes and classified by the canonical risk level. Hence, there are Class I low-risk devices, Class II moderate-risk devices, and Class III high-risk devices. In the US regulatory framework, the amount of regulatory control increases as the complexity and level of risk of the medical devices. Regarding market access, the FDA provides different pathways, the difference among them is the state of the product itself. Therefore, the pathways are as follows: Traditional 510(K) for completely new devices or old ones undergone huge changes, Special 510 (K) which regards the modifications of already authorized devices that do not need additional verification and in the end, there is Abbreviated 510(K) which regards medical devices that just need the demonstration the substantial equivalent of a

recognized standard. In addition, each medical device in the US is marked with the Unique Device Identification (UDI) system which grants the traceability and safety of the good (Amaral et al., 2024).

1.2.2 Europe regulatory framework

In Europe, several notify bodies operate under commonly agreed directives. These directives were:

1. Active Implantable Medical Devices (AIMDD), (EUR-Lex. 1990).
2. Medical Devices Directive (MDD) (93/42/EEC).
3. In vitro Diagnostic Medical Devices (IVDMD) (EUR-Lex. 1998).

In 2017, two new regulations named Regulation (EU) 2017/745 (MDR) and Regulation (EU) 2017/745 (IVDR), were issued to replace the older ones, modernize and harmonize the regulatory landscape, named Regulation (EU) 2017/745. Key changes include more rigorous pre-market assessment for devices with high-risk levels, strengthened standards for appointing and supervising notified bodies, a revised classification system for in vitro diagnostic devices, and enhanced visibility through a comprehensive European Union database (Maresova et al., 2020).

There are four product categories Class I (Low risk), Class IIa and Class IIb (medium risk) and Class III (high risk). The goods to get market access must obtain the CE mark, which ensures compliance with the European regulatory requirements. The required trials depend on the medical device classification but every good must go through post-market surveillance and be registered in the UDI and European Database on Medical Devices (EUDAMED) to enhance traceability, transparency and data transfer (Amaral et al., 2024).

1.2.3 China regulatory framework

The Chinese regulatory framework is supervised by the National Medical Products Administration (NMPA), and several notify bodies are subordinated to this large entity directly linked to the party. The regulations are designed from the 2021 “Regulations on the Supervision and Administration of Medical Devices”. Since its first version this regulatory landscape has been updated three times (2014, 2017, 2021) reflecting how the Chinese institutions are among the three major markets the most responsive to modern industry trends. The update is a symbol of the new path strongly desired by President Xi Jinping which aspires to enhance innovative high-quality medical devices as well as industrial development. The changes include the introduction of the UDI system and, more importantly, the Regulatory Science Action Plan (RSAP). The initiatives aim to enhance strategic segments within the domestic medical device industry; AI, nanotechnology, IoT software and additive manufacturing are all on the list (Zhou et al., 2022).

In China, currently exist three product categories Class I devices (low risk), the only requirement to enter the market is a record filling, Class II devices (moderate risk) which require registrations and some clinical trials and then Class III (high risk) which undergo all clinical trials and strict pre-market approval protocols (Zhou & Fan, 2023). This particular class for the most part is composed of innovative medical devices, from 2014 the NMPA enabled a green channel called "Special Approval Procedure for China's Innovative Medical Devices Trial", to prioritize the approval of such goods, later on from 2017 the inspections involved are free (Zhang & Rao, 2021).

Regarding high-end medical devices, the Chinese regulatory environment is particularly strict, for instance, to produce these goods categories in a given region, manufacturers must apply to the regional supervision and management department for a medical device manufacturing license which maintains its validity for 5 years (Yang et al., 2024). In conclusion, to get market access approval medical devices must gain the Medical Device Registration Certificate (MDRC) issued by the NMPA (Zhou & Fan, 2023). However to the current state, the process could be particularly lengthy and slow due to a general lack of professional reviewers and the unclear approval standards and regional differences in audit prices. In addition, China's regulatory framework is subject to a weak post-market surveillance process since the majority of manufacturers submit risk management documents only at the time of the good registration with discontinued follow-up after the commercialization of the product. This increases the number of accidents related to medical devices especially IoT or AI-powered goods which are easier to be attacked by external criminals (Zhang and Rao, 2021)

Referring to the main market regulatory framework as a case study, it is evident that countries and regions differ in various aspects of regulatory systems, such as quality systems, post-marketing requirements, and premarket approval processes. These differences have significant implications for medical device manufacturers seeking to enter multiple markets.

1.3 The benefit of progressive standardization of regulatory framework

The cost of lack of harmonization is relatively high and its negative side effects are reflected all over the industrial supply chain. Higher production and development prices and slower market access will reduce competition and thrive for innovation, ultimately affecting the clients. The medical devices industry's achievements to date are a pillar of modern society. Contributing to a shared and easily interpretable regulatory framework should be on the agenda of every country's government (Kaushik et al., 2010).

Harmonization of regulation is a question that world governments have always asked themselves. The first institution that took up this topic came into being in 1992 under the name of The Global Harmonization Task Force (GHTF). This pioneering international entity got together representatives from the founding nations: the European Union, USA, Canada and Japan. The organisation's first meeting took place in France in 1993 with the primary objective of creating consistency in medical device safety, effectiveness, and quality standards across their regulatory systems. The result was a shared and public document issued in the same year. Unfortunately, the GHTF collaboration was interrupted in 2012, but a milestone was achieved, and its working framework will draw the pathways for future initiatives (Amaral et al., 2024).

The legacy of this first institution was picked up by the International Medical Device Regulators Forum (IMDRF) born in 2011. The number of total participants has grown and besides the original members, countries such as China and Australia also took part in the organization. Up to now, the institutions have already published influential documents to draw standardised guidelines to design a regulatory framework that allows clinical trials to be recognized in different countries, for instance, the "Essential Principles of Safety and Performance of Medical Devices", Clinical Evaluation Guidance (IMDRF/PMD WG/N56) and Post-market Adverse Event Reporting Guidance (IMDRF/NCAR WG/N14) (Han & Bergmann, 2024).

When it comes to streamlining the medical device industry regulatory framework there are essentially three possible routes: regulatory harmonization/standardization (whereby guidelines are uniformed across different systems), regulatory convergence (whereby a system voluntarily takes another system framework) and regulatory reliance. According to the WHO definition, regulatory reliance is the act whereby the national regulatory authority (NRA) in one jurisdiction may take into account and give significant weight to assessments performed by another NRA or trusted institution, or to any other authoritative information in reaching its own decision (World Health Organization, 2024) and is the most interesting pathways to walk in certain regional areas of the world, such as ASEAN.

This method has been gaining popularity after the COVID 19-pandemic. The global event obliged countries from different GDP lawyers to collaborate since the low and middle-income countries faced huge difficulties in medical device suppliance. During the emergency, time was running out fast, and the government had to streamline market access processes. From this experience and based on the assumption that ASEAN will become the biggest medical device market in the world shortly, building regulatory frameworks of developing countries through regulatory reliance on more developed and modern ASEAN national regulatory associations (NRAs) could be a crucial step ahead (Xu et al., 2022a)

In this context extremely important is the role of the Chinese NMPA, which is aligning itself to international regulatory practices, particularly the ones coming from the West, which are located the most developed player in the industry. For instance, in 2013 China joined the cited IMDRF and in 2017 NMPA joined the International Conference on Harmonisation and secured a committee position in 2018 fostering their contribution to global standards with active participation in the development of guidelines Postmarket Clinical Follow-Up Studies in 2021. Therefore, China and NMPA are settled to become the major leading forces in regulatory standardization in Asia, creating a bridge from west to east (Xu et al., 2022a)

In conclusion, the potential benefits of a shared and standardized regulatory system are evident, firstly easier, economical and quick market access will be granted enhancing the globalization of the industry. Second, companies will save financial resources from this stage of goods development and could invest more in R&D, which is located where the majority of the value of the final products. All these factors combined will be reflected in better client experience, more affordable prices and more equalitarian access to health.

1.4 Medical device market drivers

As cited in the previous sections, the medical device market is heterogeneous, composed of different goods, divided into categories with different purposes and applications, hence numerous variables influence the trend and development. The ultimate scope of the industry is to constantly adapt and produce solutions to preserve and enhance global health, therefore, starting from this unequivocal assumption we can draw in this section a theoretical overview of all the potential market drivers.

People's health has always been the fundamental driver of the industry, to a certain extent the most diagnosed diseases, settle the market trends and development. Based on expert evaluations nowadays, people's health is especially threatened by their lifestyle. Extended working hours, sporadic physical activity and unhealthy diets are the main triggers of chronic diseases, which are expected to be the cause of death for around 70% of the global population and their global burden on national healthcare systems (NHSs) is expected to hit 60% by 2030. This condition specifically affects highly developed countries namely the United States and Europe nations where obesity, diabetes and oncological disease rates are increasing (Ashter, 2022). Moreover, the world's ageing population also represents a market driver. This geriatric phenomenon will mainly affect developing countries such as China and India, forcing a rapid evolution and growth of the medical device industry, in these countries governments are already facing the pressure of a large size population (Chen et al., 2020). This topic is dealt with extensively in later sections of the thesis.

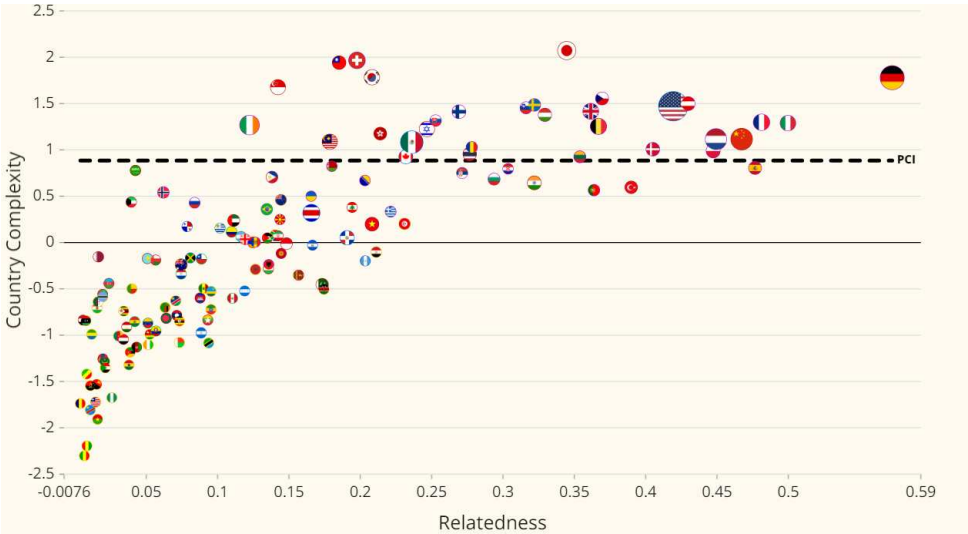
Regarding people's health conditions and market drivers, it is necessary to mention the recent overcoming of the COVID-19 pandemic. Besides the catastrophic consequences familiar to most, this worldwide event enhanced people's healthcare awareness, translating to an increase in healthcare expenditure which directly benefits the net revenue of medical devices domestic and international sales (Awasthi & Stanick, 2022).

A higher GDP is another variable related to an increased dimension in national healthcare expenditure. The increase in pro-capita revenue usually generates an economic expansion of the middle-class population. This population segment now owns the purchasing power to invest in personal health, moreover, a richer country has more room to optimise or reorganize, if necessary, insurance coverage and the reimbursement system, two of the nation's infrastructures that play a key role in the industry (Sapkota et al., 2022).

The healthcare insurance and national reimbursement systems do not directly represent medical device market drivers but influence the sector. Obviously, as in every aspect mentioned in this section, they are susceptible to regional variations. Medical insurance is responsible for collecting, managing and paying medical expenses, which means that it is one of the government's tools to relieve the pressure on pro-capita healthcare expenditure. A well-structured and robust insurance system can ensure long-term sustainability in the medical device industry within a nation, consequently enhancing revenues (Jiang et al., 2019). The extension and sustainability of medical insurance is related to government healthcare expenditure; hence this value represents itself as a market driver of the industry. More revenue generates more resources that manufacturers can invest in these two aspects of the public health system (Xiao & Yuan, 2022). Reimbursement systems impact the growth rate of certain medical device categories rather than others, it depends on whether goods are facilitated to be enrolled in the reimbursement list, then it is straightforward to identify the advantage on the market penetration for those goods selected (Awasthi & Stanick, 2022). These assumptions are supported by data that show how a rise of 1% in government health expenditure for developed countries generates a corresponding increase of 1.49% in the technical sophistication of medical device exports. Developing countries follow closely with a 0.88% improvement based on the same 1% increase (Xiao & Yuan, 2022).

More revenue is often translated into more room for the development of technology complexity of medical devices, which has resulted as a powerful market driver. R&D and human capital are the foundation of medical device development, enhancing the technical complexity of this product category leads to the strengthened global competitiveness of the medical device industry, therefore beyond individual nations, the global medical device industry benefits as a whole.

Figure 2: Global map of medical device complexity of each country



Source: OEC (2024)

Countries with a higher level of medical device complexity create a competitive edge, translating into greater market share, increased profitability, and sustainable growth. This aspect is related to relatedness. A high rate of relatedness is predictive of the probability that a country increases its exports of high-end goods (OEC, 2024)

Three main lawyers build R&D activities in the industry. The core component is knowledge and technology, then there are the actual actors such as government, firms' human capital (researchers, suppliers), medical institutes which implement the new technologies, and then there are the institutions which are responsible for another key process of development which is the knowledge diffusion (Cheong et al., 2020). Governments and private sectors in both developed and developing nations must collaborate to prioritize funding for education, training programs, and technological research. Policies that incentivize innovation, such as tax breaks for R&D expenditures and grants for skill development, can accelerate progress in this domain (Xiao & Yuan, 2022).

Similarly, international partnerships and knowledge exchange initiatives can further enhance technical capabilities, especially for developing countries aiming to close the gap with more advanced economies. This need perfectly justifies the M&A (merger and acquisition) ongoing trends in the industry, reaching its maximum growth rate of 178% in 2017. These operations allow the biggest company to diversify areas of production, penetrate new markets safely and efficiently, and scale its revenues (Awasthi & Stanick, 2022).

Data support these market drivers, the gathered data shows that in developed countries, human capital exerts contributed with a 0.83% improvement for every 1% growth. This underscores the importance of

a skilled workforce capable of leveraging advanced technologies and fostering continuous innovation. In developing countries, human capital takes an even more prominent role, driving a 1.42% increase in technical complexity for every 1% growth. These findings highlight the dual necessity of investing in both human development and the healthcare sector to cultivate the expertise and infrastructure needed to compete in a technology-intensive global market. Moreover, R&D investment acts as a critical enabler in both contexts, bridging gaps in technical capability and fostering the creation of cutting-edge solutions tailored to emerging market needs (Xiao & Yuan, 2022).

Regulatory frameworks play a crucial role in this industry, R&D itself is mainly directed by strict regulations, therefore they can be a double-edged sword in the development of the market. At the same time, regulatory frameworks can be considered powerful market drivers when they are designed to simplify innovation and enable to create a more interconnected trade scenario. A path of open-up policy and regulatory normalization can be an important tool to incentivize nations to invest in development and trade, which would benefit on a large scale the entire industry (Awasthi & Stanick, 2022). These policy and regulatory aspects are closely linked to Foreign Direct Investment.

Foreign driving investment (FDI) is another market driver for the medical device sector, especially for developing countries. By common sense, FDI is conducted by a technologically advanced country that sees potential in a developing country. While the advantage would seem to be only for the investor, the FDI is an incredible opportunity to allow the recipient country to use capital and know-how to bridge the technology gap and begin planning domestic development from the investor's prior experience (Torsekar, 2018). Building on the foundations laid by these forerunners enables a swifter convergence with the technological frontier, minimising inefficiencies along the way. Through this transformative process, developing nations can redefine their roles within the international division of labour, transitioning from peripheral participants to influential contributors (Yeom et al., 2021).

In the end, cultural diversity has emerged as a powerful market driver. Its potential is attributable to its power to enhance advancements in the technological complexity of goods. Diversity naturally fosters varied economic activities and expands the frontiers of innovation while elevating the technical sophistication of exported goods which always reflects positive gains in net revenue (Xiao & Yuan, 2022).

1.5 International trade of medical device, preliminary environmental analysis

Since 2018, international trade has shifted towards a decoupling trend and the worldwide attitudes of national governments favouring unilateral nationalism supported by protectionism policy, has resulted in friction in world trade. The international trade of medical goods is a critical component of the medical device industry, this section provides a brief environmental analysis.

Disruptive global events, namely the 2019 Brexit referendum, the US-China trade tensions, and the COVID-19 pandemic, precipitated this scenario. While Brexit and the US-China trade conflict were predominantly economic, the unprecedented emergence of the COVID-19 pandemic exerted a substantially more comprehensive holistic impact across global systems. In particular, the medical device sector experienced a transformative disruption, characterized by challenges in supply chain dynamics, production capabilities, and international distribution networks, however, the inherent contradiction with the industry is that in the long term medical device market benefited from this event (Bai et al., 2022).

Given the assumption that compliance with the regulatory framework governs the international trade of medical devices. When on March 29, 2019, the Great Britain Brexit referendum resulted in the exit of the country from the European Union, were immediately concerned about this aspect and paved the way for a “no deal” scenario in the import and export of medical devices. All countries outside of the EU are considered third countries, therefore all the export products coming from those locations must comply with the CE certification and UK-notified bodies are no longer legally allowed to release it. Consequently, obtaining this validation from EU institutions represents additional financial burdens for UK manufacturers and vice versa for EU counterparts (Awasthi & Stanick, 2022). These disincentives are also reflected in statistical analyses. Taking as an example orthopaedic appliance (the most traded medical device in the UK), the exports accounted for £1.9 billion compared to the imports accounted for £2.87 billion with a total trade deficit in medical apparatus with imports exceeding exports by approximately £3.8 billion, demonstrating this particular national policy resulted in harmful consequences (Statista, 2024).

Further broadening the perspective, the US-China trade war, caused by the first Trump administration in 2018, based on strategic product category imposed a variable rate between 7.5% to 25% of board tariff on Chinese imported goods, accumulating a total additional import cost of $34 billion worth, triggering a Chinese answer which escalated the trade war. In September 2019, the pressure kept rising reaching over $119 of taxed goods from China, demolishing Exports to China which represented 9.5% of the total exports of the US with a total shipment value of US$4.5 billion (Awasthi & Stanick, 2022). Already in the summer of 2019, the tension was exploited when the manoeuvre involved high-end medical technology such as X-ray generators, anaesthetic devices and optical instruments (Zhang & Rao, 2021). The groundbreaking consequences on the industry supply chain and service reliability imposed in the end to exempt nine types of medical devices from the 25% tariffs including surgical, radiotherapy, and dental equipment. Even if the list contained a few healthcare products, the board tariff was especially focused on the raw material which displays a fundamental role in the production of medical

devices. After the Trump mandate, the Biden administration has adopted a more moderate approach, taking care of the search for dialogue with the Chinese counterpart, and paying great attention to the most sensitive sectors, trying to treat an open wound of loss of around $860 million in Chinese imports to the U.S. and nearly $5 billion in exports to China (FIME, 2018). However, the renewed election of Donald Trump paved the way for a new dive in the trade war, since the 47° President of the US has recently imposed 10% duties on Chinese goods. The expected answer from the Asian counterparts is the rise of duties for US imports however, to date the Chinese government has opened to dialogue and diplomatic revision (Reuters, 2024).

In 2020 the world economy was disrupted by the COVID-19 Pandemic unforeseen event. The major instruments that mankind utilized to contain and reverse the plague were medical devices. Goods such as respirators, surgical facemasks and rubber gloves represent the basic equipment that contrasts the spread of the coronavirus. During this period medical device production was the most important sector of the entire Healthcare industry. The pandemic shook the consciousness of people, which started to look upon the medical devices industry as a valuable measure to define a country's welfare level and scientific and technological progress (Hu, Qiu & Zhou, 2022). With great uncertainties, from an economic perspective, this event erupted again in protectionist policies. To give a hint, it has been recorded that a total of 54 governments have implemented export restrictions and trade barriers on medical supplies and medicines (Bai et al., 2022).

The objectives of this intervention were securing domestic supplies, protecting the integrity of the supply chain, and enhancing national security and self-reliance. During a period when most of the sector's revenue was nullified, ensuring that the domestic medical device sector was efficient and produced economic return was crucial.

Chapter 2: Medical device market, review of quantitative analysis

2.1 Methodology

The data gathered and presented comes from secondary sources, specifically databases, analysis sheets and research papers. This chapter aims to convert this data into an understandable review of a medical device market's quantitative analysis. Due to the nature of my academic background, no further statistical operations or mathematical models were applied by myself. Economic model operations have been carried out in the third author's papers, results are presented descriptively, offering a comprehensive exemplification of the models that led to them and the key variables for understanding the industry aspects. Accordingly, authors and sources will be cited. The section of this chapter is structured as follows.

The first section is a holistic and static description of two main topics. Firstly, the findings regarding the net value of the medical device market, its growth rate, and forecast size are displayed. In compliance with the thesis objective, the second topic of the static description is a detailed analysis of the international trade market. The exchange of goods is defined as a trade network, to understand the output, features and relationships that govern this network, it is crucial to share some fundamental concepts. The trade network is composed of nodes, a node is a unit representing each country involved. These nodes are connected to a certain degree describing the relationship between them. The degrees utilized in this chapter are three: degree, in-degree, and out-degree. Respectively they defined strength (overall rank or importance of the given country in the network), in-strength (import capabilities) and out-strength (export capabilities), besides the basics there are other indicators such as clustering coefficient, closeness centrality, betweenness centrality, all indicators describe the tightness of the network and the path length between each node (Bai et al., 2022).

The medical devices international trade network is also described from a dynamic point of view, this dynamic approach allows us to understand the major players and how they influence the other nodes. The results presented by the dynamic analysis are derived from two studies: Bai et al. (2022) and Hu et al. (2022). They are obtained by the implementation of two fundamental models in a network analysis the "linear threshold influence model" or "LT model" (Bai et al., 2022) and the "inter-dependence index analysis" (Hu et al., 2022). The models are briefly explained to ensure a comprehensible reading of the data.

The LT model is a framework which shows the level of dependency between nodes through an individual's behaviour under the influence of their neighbors. To apply the model, a fixed value is given

to a threshold representing a country's capacity to withstand a variation (in the analysis conducted is settled to withstand an import reduction) (Bai et al., 2022). In a trade network environment, the model works as follows. Consider a network composed of three countries (nodes) which cover these roles: Country A is a major exporter; Country B is one of the importers from country A and Country C is the major importer from country B. It means that Country B has a low dependency on Country A, however, if Country B reduces its exports due to an original reduction in exports in Country A, then the influence on Country C will be massive since it depends entirely on Country B for imports. It means that Country A has a greater impact than Country B, but Country B has a greater influence on Country C compared to Country A. Countries in the model are classified into two conditions, the normal condition and the avalanched condition. In the first spread step, the exports of Country A are reduced, consequently, if the import reduction of Country B is more than the threshold value, the state of Country B becomes avalanched. The model stops when there are no more avalanched countries. Therefore, the number of avalanched countries allows the measurement of the influence of a country in a specific region of the network, and it appears only when the import value decreases in country B is more than the threshold (Bai et al., 2022).

In addition, a brief analysis of the main area of interest is conducted combining static and dynamic aspects to produce a comprehensive scenario (Bai et al., 2022).

In conclusion, a paragraph is exclusively dedicated to China to understand how influent is in the medical device trade network and the bilateral China interdependence with the other countries, the result presented was obtained by Hu et al. (2022) utilizing the interdependence equation.

The interdependence equation calculates an index, DrGLi,j, ranging from 0 to 1, if the value is equal to 0 signifies a one-way trade relationship (only exports or only imports), on the other hand, a value of 1 denotes equal export and import volumes, which means the strongest interdependence (Hu et al., 2022).

To ensure the coherence of economic measurements throughout this chapter, the selected monetary value is US$, for readability, the notation “$” will be used throughout, unless otherwise specified.

2.2 Global medical device market size

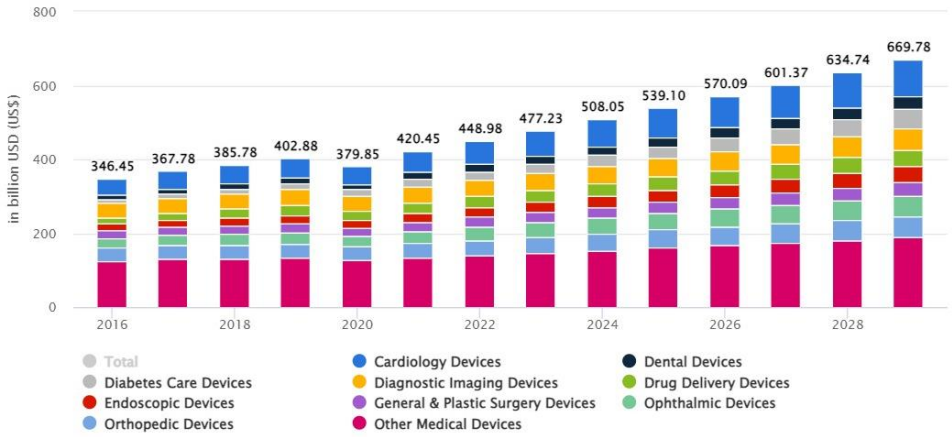
The medical device market is a branch of the healthcare industry and is set to grow. This growing trajectory is attributable to the sector's role in the prevention, diagnosis, and treatment of human diseases. These factors make the segment one of the most profitable and safe in the world. Therefore, these features are reflected in the statistics gathered to build up this section.

After surviving a disruptive decrease in international trade net value during the pandemic, in 2024, industry reports display a cumulative market value of $508.00 billion, symptoms of a robust and resilient

industry, which has benefited in the long term and was able to bounce back after the event (Statista, 2024).

The experts forecasted a stable upward trend, sitting at a compound annual growth rate (CAGR) of 5.68%, expecting to hit $669.70 billion of global output by the end of 2029 **(Fig.3)** (Statista, 2024). Almost 88,5% of the total revenue is produced by healthcare infrastructure like hospitals and clinics supply, the rest is almost entirely covered by the purchase of single end-user (Biospace, 2024).

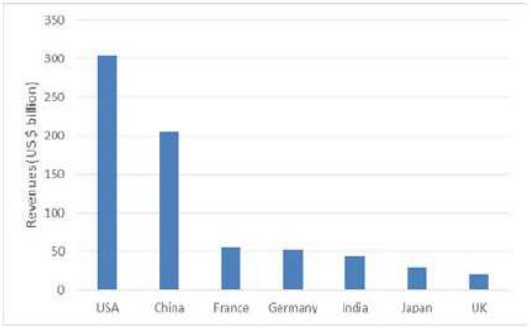
Figure 3: Forecast of the global medical device market value

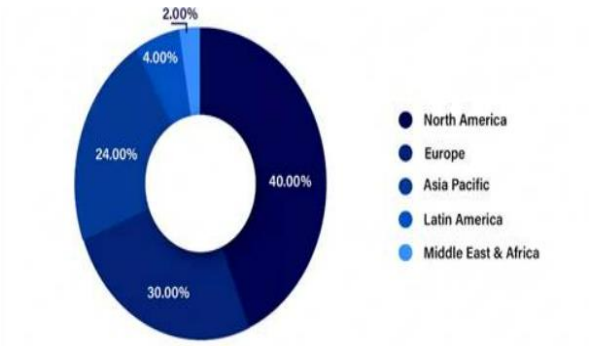


Source: Statista (2024)

From a net value perspective, the medical device market is characterized by the geographic dominance of certain areas of the world. Almost 80% of the goods purchased in the sector are from highly developed countries, United States, European nations and China represent the bigger stake, with India quickly closing the gap **(Fig. 4)** (Hospodkova et al., 2018).

Figure 4: Top 7 Market medical device revenue & forecast for 2030 and medical device market shares by region 2023





Source FIG 4A: Hospodkova et al. (2018)

Source FIG 4B: Bio Space (2024)

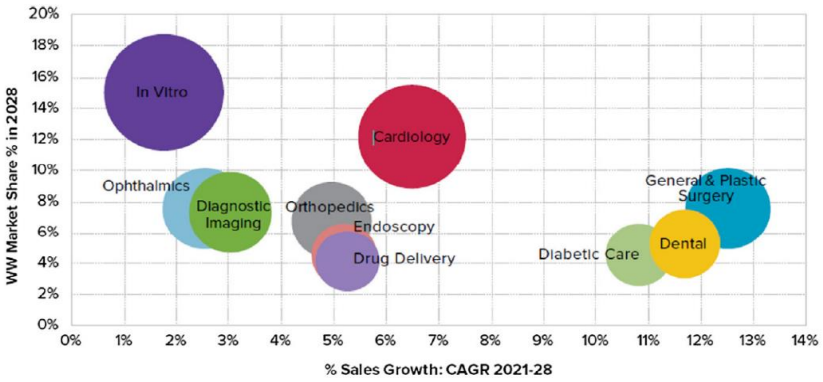
As shown by the doughnut chart **(Fig 4B)**, North America occupies the biggest part of the market with a 40% share followed by Europe with 30%, the rest of the world is divided into three regions. Among them, the biggest contributor is the APAC with an overall share of 24% (Biospace, 2024). Latin America and the Middle East account for 6% of the total, where respectively the state with the highest net value is Brazil with $12.2 billion in 2022. Meanwhile, Turkey, Saudi Arabia and the Emirates States reach $10 billion in the same year (Awasthi & Stanick, 2022).

Closing the scope by looking at **Fig 4A**, in 2030, the US will own the biggest piece of the market and will produce the higher global revenue accounting for around $300 billion, followed by China ($200 billion). However, China holds the record of being the fastest-growing market in the history of the medical device industry. From a modest economic footprint of barely 1.4% of its domestic GDP and a mere 3% global market presence in 2012, China's position in the medical device sector is undergoing a remarkable transformation. Industry projections paint an ambitious picture, suggesting the nation could occupy a quarter of the worldwide market by 2030 (Hospodkova et al., 2018). Reporting forecasted global earnings, marginally lower than $50 billion India comes behind the two biggest players in Europe: France and Germany (Lalwani & Suvarna, 2021).

2.3 Product-based market segmentation of medical device

With the words medical device is asserted a specified goods category, however within there are different segments. To draw a comprehensive picture of the industry this paragraph presents a product-based market segmentation of the sector. Each product type is described with its current market size, forecasted growth rate, and regional insight since national variations in regulatory frameworks and healthcare infrastructure significantly influence the adoption rates and market penetration of different device categories. This section also helps better understand the market drivers involved. Indeed, a well-structured market segmentation analysis reflects the industry's current market drivers and is key to acknowledging the market demands. To start the dissertation **Fig. 5** gives an overview of the major product segments in the industry.

Figure 5: Global market share and sales growth by medical device segment (2021-2028)



Source: Wreh (2023)

Fig. 5 is a bubble chart constructed as follows. On the "Y" axis is presented the forecasted market share in 2028, and on the "X" axis is presented the forecasted growth rate. As previously cited, medical devices are an agglomeration of different goods, however in terms of market share only a few categories take the biggest proportion. Data shows that the top seven segments represent together 60% of the total market, these seven categories are In-Vitro diagnostic devices, diagnostic imaging, orthopaedics, ophthalmology, general and plastic surgery, and endoscopy medical devices (Awasthi & Stanick, 2022).

IVDs currently occupy the biggest share of the market accounting in 2022 for a total net sale of $77.6 billion (Awasthi & Stanick, 2022). Their growth rate is variable and forecasted between 3 to 4.5% per year, this variation depends on the region taken into consideration. Their total value decreased compared to the pandemic era when these goods presented an even higher market share, nonetheless, they still will remain the most sold segment with an expected value of $113.4 billion and a total share of 15% (Wreh, 2023). The peak reached during the COVID-19 pandemic is mainly attributable to their role in the emergency. The most sold IVD product in this period were COVID-19 rapid antigen tests, it is easy to imagine the crucial impact and vast employment of these goods, worldwide China was the biggest beneficiary from this situation since is one of the main manufacturers (Yang, Ouyang & Wu, 2024). IVD are employed for diagnostic and study purposes and the spectre of the complexity of this product category varies (World Health Organization, 2024)

These goods are for the most part low-end medical devices, therefore in countries with vast labour forces such as China, these medical device segments will be prominent. On the other hand, on a higher level of complexity, they can be utilized for diabetes, molecular and histochemistry diagnostic activities which account for 98% of global revenue for these goods. The main market drivers of this product

category are the recent awake people's consciousness on health which stimulated ordinary people to increase the frequency of health checkups and similar activities, this aspect combined with the increase in lifestyle-related diseases such as cardiovascular or diabetes has made this segment the most important in the industry. From a geographical perspective as already cited, the low-end applications of IVDs, APAC and LATAM have a cost production advantage, in addition, the expansion of these developing country healthcare systems will increase the demand for IVD devices. On the contrary, in developed countries, such as the US and Europe, constant cuts to reimbursement systems and deep changes in regulatory frameworks will affect negatively the growth of this segment (Awasthi & Stanick, 2022).

Cardiology medical devices with a global share in 2024 of 12.2% are the second largest segment (Statista, 2024). Compared to the 2022 IVD net value these good categories accounted for slightly less but nearly $69.9 billion. On the other hand, the CAGR of this segment is way higher and is settled at 7% (Wreh, 2023). Cardiology medical devices can be segmented into two main categories: therapeutic and surgical devices. The most common are cardiac rhythm management and diagnostic instruments such as electrocardiograms (ECGs), implantable cardiac monitors, pumps and heart lungs machines. The first cited sub-segment is the most profitable with 76% of total shares for the good category. The main end-users of these products are high-volume buyers, namely hospitals and ambulatory surgical centres. Recently low-volume buyers are on the verge due to a technological development trend in home healthcare and low-volume buyers (Fortune Business Insight, 2024).

These goods category are all high-end medical devices, therefore, to develop and produce these goods there is the need for advanced infrastructure, a high level of know-how skilled labour forces and a highly developed supply chain. These aspects are the key market drivers of this segment, which found prosperity in highly developed countries such as the US Europe and recently China which is settled to become a major player in high-end medical device productions (Awasthi & Stanick, 2022).

Diagnostic imaging is the third biggest segment in the industry, similar to IVD, their value picked in the recent past. In 2017 their market size accounted for 9.8%, decreasing to 8.6% in the current year (Statista, 2024). This trend soon will be inverted since the growth rate of this segment is modest but positive (3%). The reason behind an overall decrease in the growth rate is mainly attributable to the new consciousness of people around health, indeed the radiological effects on the human body, which recently have a big resonance in the end users, combined with a shortage of well-trained sanitary operators have generated this limited growth (Awasthi & Stanick, 2022). However, these remain one of the most important segments for future development of the medical device industry.

The fourth place is occupied by orthopaedics devices, with a net revenue of $49.8 billion by the end of 2022, and a total market share of 9% reached in 2024 (Statista, 2024). Notable is the growth rate of this

good category equal to 5%, this high growth rate is mainly attributable to the geriatric phenomenon of ageing of the world population, which represents one of the most powerful market drivers of the industry (Awasthi & Stanick, 2022). Elderly individuals are more prone to suffer orthopaedic disorders such as arthritis, osteoporosis or injuries in general. Therefore, from a regional perspective, in countries such as China, Japan, and Korea, this kind of medical device will have major improvements in market revenue (Jakovljevic et al., 2021). In addition, technological development plays a crucial role. With the emergence of advanced technologies such as robotic surgeries, ortho-biologics, smart sensor-enabled devices, implants and 3D printing techniques, these achievements will increase investment and growth in this segment (Awasthi & Stanick, 2022).

The top 5 rank is closed by ophthalmology medical devices. This product category comprehends all diagnostic and treatment of optic diseases medical devices. The primary growth factor for this product is the already cited ageing population trend also known as the third demographic transition, the geriatric condition will increase significantly the worldwide cases of glaucoma, cataracts, macular degeneration and diabetic retinopathy, therefore the most profitable market region soon will be the APAC area, moreover, technological advancements such as laser-assisted surgery, multi-wavelength diabetic retinopathy treatment, ultrasound phacoemulsification and femtosecond laser surgery will further increase the revenue and market share of the ophthalmic device segment, especially in high-developed regions namely the US and Europe Nations (Awasthi and Stanick, 2022). In 2022 the total net value of ophthalmology medical devices accounted for $39.7 billion, with a modest growth rate of 3%. This segment is forecasted to occupy by the end of 2024 a market share equal to 7.1% (Statista, 2024).

In this landscape, a notable mention is diabetic care, dental and plastic surgery medical devices. As depicted by **Fig. 5** these three categories, compared to the top 5 biggest medical devices segment occupy a relatively small section of the industry, however by far they have the highest growth rate among all. Following an ascending order, diabetic care medical devices growth rate is 11%, for dental goods is 12% and 13% for plastic surgery instruments. The forecasted growth of diabetic care is due to the world population's medical conditions. The latest insights reflect that an increased rate of obesity in the population and cardiovascular diseases, especially in the US, will play a significant role in the expansion of this segment share. On the other hand, the gradually higher GDP of developing areas will open access for more people to dental and plastic surgery. Again, technological development is another pivotal factor. It is predicted that the latest achievements in monitoring and delivering insulin will also enhance the diabetic market. Regarding dental and plastic surgery medical devices, the main market driver is renewed attention to health combined with an empowered new middle class in developing countries who are willing to spend more on those kinds of medical devices (Wreh, 2023).

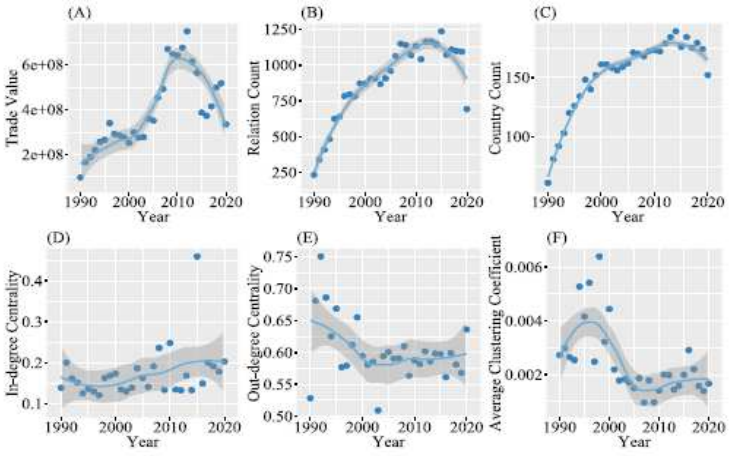
Neurological medical devices deserve particular attention. By the end of this year, neurology medical devices will be the least profitable segment of the whole industry, sitting in the rank with a market share equal to 2.7% (Statista, 2024). In 2022 the global revenue of this segment was approximately $13 billion, however, thanks to an increase in neurological disorders linked to the ageing population this segment is settled to become one of the most profitable in the industry (Awasthi & Stanick, 2022).

2.4 International trade of medical device, review of quantitative analysis

This part of the analysis delves into the empirical description of international trade in medical devices. The medical device international trade thrived especially from 2001 to 2015 with an average annual growth of 7.23%, then gradually declined until 2020 and started growing again in 2021. Alongside the increase in shares also the participating countries have risen, reaching a summit of 230 nations involved who share a total amount of 5,640 trade connections (Hu et al., 2022).

The medical device trade network has evolved into a complex global ecosystem with multiple sectorial interconnections. To date, the overall output of the international medical device trade is rising, and the countries involved are increasing (Statista 2024). With smarter and more developed logistics solutions and supply chain design efficient commercial routes are created. But the medical device industry is probably the most sensitive and diversified in the world, therefore conclusion cannot be drafted by only looking at the large number of revenue output, and the scenario is deeper than expected. An insightful insight into the evolution of the trade landscape is given in **Fig. 6**.

Figure 6: Overview of the Global Medical Device Trade Network from 1990 to 2020



Source: Bai et al. (2022)

Fig. 6 is divided into panels; each represents an indicator and its evolution over time. Panel A shows a steep increase from 1990 to 2014 when the medical device exchange peaked in 2014-2015. After 2-3 years of plateauing, the market experienced a decrease, hitting bottom in 2019 with the explosion of the COVID-19 pandemic. It started again rising only after 2021; however, the data shown in the panel stopped in 2020 (Bai et al., 2022).

If analyzed together, Panels B-C-F produce a remarkable outcome. The number of trade relationships (Panel B) and trade partners (Panel C) has multiplied over the years, reflecting a good level of interconnectivity and a great number of countries involved. The reduced proportion of growth in recent years can be attributable to a certain degree of saturation and the influence of worldwide dimension events on the industry (Bai et al., 2022).

Panel F shows a steep decline in the clustering coefficient followed by a relatively stable plateau indicating significant disparities in the global medical device trade market, this means that a small number of countries dominate the majority of trade value. Furthermore, despite some small fluctuations, stability after the decline in the average clustering coefficient suggests that trade relationships between countries have become more fragmented and less interconnected on a global scale. In addition, regional trade blocs have emerged. In these specific regions, countries have developed stronger, more interconnected trade relationships with their geographically bigger neighbours (Bai et al., 2022).

These disparities in the trade network are attributable to the difference between developed countries, which monopolised the international medical device trade, and developing nations, which still play a marginal role in the industry. The situation is particularly notable in exports and is given by the data as follows: in 2018 countries such as Europe, America, Japan and Korea accounted for about 85% of the total medical device export market, on the other hand, the developing areas accounted for only 15%, with the BRICS group occupying 7% of this section and 5% the rest of the world. In 2018, the total trade net value of developed countries was $340.99 billion compared to $40.35 billion for developing areas (Xiao & Yuan, 2022).

This data reflects also on the trade surplus and deficit balance. The only countries which present a consistent trade surplus are high-end medical device producers, meanwhile mid and low-end manufacturers have experienced fluctuations in surplus rates. Developing countries maintain a trade deficit in medical devices, particularly in high-end equipment. However, they show a trade surplus in medium and low-end devices. This pattern reflects their relatively recent entry into the market, positioning them primarily in lower-value segments of the global medical device supply chain. Measuring this gap also demonstrates that high-end medical devices represent the main source of revenue in the industry (Xiao & Yuan, 2022).

Taking as an example, the data gathered in 2018 in developed countries the total value of high-end medical devices exported was around $127.4 billion, generating a surplus of $18.31 billion. On the other hand, the trade volume of exported medium and low-end medical devices produced a trade value of $52.62 billion with a net revenue of almost $74 million. Instead in developing countries in the same year, the high medical devices exported net share was way lower, equal to $7.17 billion and did not generate a profit, indeed a loss of $1.17 billion was recorded. On the contrary, the medium and low-end medical devices export generates a total value export of $8.34 million and a revenue of almost $24 million. These data depict how crucial is the segment of high-end medical devices and how the market is governed by the major producer country of these goods (Xiao & Yuan, 2022).

Panel D-E represent respectively the export and the import evolution, during which time both increased and eventually reached a plateau after 2020. However, what is worth noticing is that exports compared to imports are way higher and this shapes perfectly the main features of this market, therefore, the international medical device trade market is export-oriented, and these meaningful characteristics are attributable to the nature of the goods indeed to produce medical devices in vast quantity, a given nation must dispose of a high level of technological manufacturer centre and own a labour force with the correct know-how that can achieve and maintain high efficient on every layer of the industry supply chain (Bai et al., 2022).

Moreover, the pandemic's impact on global device trade patterns reveals an intriguing contrast: while market size underwent dramatic changes between 2019 and 2020, the shifts in import competition and export monopolization were less pronounced. Notably, the COVID-19 outbreak strengthened the monopolistic nature of export channels significantly. Meanwhile, the import channel competition saw only a modest increase in intensity. These patterns point to a revealing dynamic: underdeveloped nations demonstrated heightened vulnerability in the face of pandemic-related disruptions, as evidenced by their weakened position in the global trade network (Gereffi, 2020).

Therefore, the shape of the medical device trade is clear, this clearness is attributable to its distinctive characteristics. The role of the country representing the major forces in the trade network is firmly fixed. These countries obtain this centrality due to their potential as exporters and importers of medical devices **(Table 1)**.

Table 1: Top 10 export countries (on the left), Top 10 import countries (on the right) from 2001 to 2020

Rank	2001		2005		2010		2015		2020	
	Out-strength	In-strength	Out-strength	In-strength	Out-strength	In-strength	Out-strength	In-strength	Out-strength	In-strength
1	United States of America	United States of America	United States of America	United States of America	United States of America	United States of America	United States of America	United States of America	United States of America	United States of America
2	Germany	Germany	Germany	Netherlands	Germany	Germany	Germany	Germany	Germany	Germany
3	Japan	Japan	Netherlands	Germany	Netherlands	Netherlands	Netherlands	Netherlands	Netherlands	Netherlands
4	Netherlands	Netherlands	Ireland	Japan	France	Japan	China	China	China	China
5	France	France	France	France	Switzerland	France	Belgium	Japan	Ireland	Japan
6	Ireland	United Kingdom	Switzerland	United Kingdom	Ireland	China	Ireland	Belgium	Mexico	France
7	United Kingdom	Italy	United Kingdom	Italy	Belgium	Belgium	Switzerland	France	Switzerland	Belgium
8	Switzerland	Canada	Japan	Belgium	China	United Kingdom	Mexico	United Kingdom	Belgium	United Kingdom
9	Mexico	Belgium	Mexico	Canada	Japan	Italy	France	Italy	Singapore	Italy
10	Belgium	China	Belgium	China	Mexico	Canada	Japan	Canada	France	Canada

Source: Hu et al. (2022)

The top 5 spots in **Table 1** present more or less the same nations. Nowadays, the top 5 countries: the US, Germany, the Netherlands and China together account for 71% of the total export revenue in the industry, extending the proportion to all the top 10 countries involved in the percentage rise to 90%. This rank is indicative of an elitarian hierarchy. As already explained, these countries are all located in high-developed world areas due to the necessity of highly developed and expensive facilities and knowledge to produce high-generative revenue medical devices (Hu et al., 2022).

A notable mention is Estonia, since the country has made the most interesting moves, indeed in 2010 this country wasn't even ranked in the high spots however in 2020 produced a total export value of $47.85 million (Bai et al., 2022). This incredible scale can be explained as Estonia represents one of the most promising European markets for the R&D development of medical devices attracting FDI which contributes to medical device production (Awasthi & Stanick, 2022). On the other hand, the US in the same decade lost more than 50% of total export revenue. As cited in **section 1.5** this downgrade is attributable to outside events with direct effects on the medical device export, in chronological order the Donald Trump administration's 2018 aggressive commercial policy and the spread of the COVID-19 pandemic one year after.

In 2020, Asian countries, specifically China, India, Japan, and Kazakhstan emerged as the leading regional block commanding 27% of medical device imports. European nations followed closely at 25%, marking a significant departure from historical patterns where other regions had dominated the market. Overall, the top 10 importing countries controlled 50-70% of the total import volume (Bai et al., 2022).

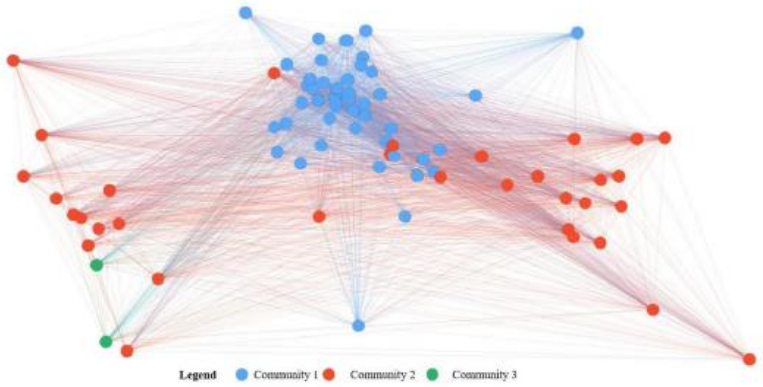
China and India's escalation in the medical device market has a similar path, both nations are characterized by a massive population who will need shortly super-efficient and stable healthcare systems, also these giants' developing economies play a crucial role in their neighbor countries' NHS as detailed depicted in the further section of this study. On the other hand, this shift relief pressure and revenue from the all-time export giants such US who scale the import rank because are highly

industrialized and have production means for advanced medical technologies, imported mainly middle- to low-end products and raw materials to produce high-end products based on cost reduction considerations.

By drafting a conclusion for this first part of the analysis, we can look at the absolute value of imports ($199 billion) and exports ($307 billion) in 2020. The net value of total exports was higher than imports, confirming the export-oriented characteristics of the market. The general deduction in international trade value is attributable to protectionist events but also the gradual development of efficient domestic NHS and medical device production, allowing developing countries to not solely rely on exports. (Bai et al., 2022).

However, this imbalance between export and import resulted in an intricate network of interdependencies based on territory and influence proximity, this trend has led to the creation of three distinct communities displayed in the trade space as depicted by **Fig. 7**. Two large communities in the Asian-Europe countries (community 1) the Pacific-Rim countries (community 2) and a small community in the South American countries (community 3), represented as follow **Fig. 7**, obtained with the application of Louvain Modularity Algorithm by Hu et al (2022).

Figure 7: Medical device international trade space



Source: Hu et al. (2022)

Community 1 represents the largest and most interconnected group, which dominates the industry through robust export activities and extensive trade relationships. The major players are Germany and the Netherlands, with a combined export net value of around $4 billion. This group generates 46.53% of worldwide medical device exports and establishes almost three-fifths of all global trade connections. The strength of this first cluster is pointed outward, but the internal exchange is also quite impressive

featuring major buyers like the UK, Italy, Slovakia, and Romania. Overall, 40% of participating nations import medical devices valued above $100 million (Hu et al., 2022).

Community 2 is probably the most interesting among the entire trade network because its core is divided between China and US. Its influence spans Asia, Europe, and the Americas encompassing 33 distinct regions and countries. On the other hand, compared to community 1 own fewer trade connections accounting for 40.43% of total connections but contributing to 53.13% of global medical device exports. The community's hierarchy is clearly defined, with the United States serving as the primary hub, followed by China in the second position and Japan emerging as the third most significant exporter (Hu et al., 2022).

Community 3 is composed of two small players in the LATAM area, namely Chile and Peru and plays a marginal role with both global imports and exports not reaching 1% of the global trade output (Hu et al., 2022).

Starting from this assumption, the following paragraphs will delve into an empirical description of those characteristics. Detailed data are given as follows **Table 2**.

Table 2: Nodes measure of global medical device trade networks

Category	Measure	2001	2003	2005	2008	2010	2013	2015	2018	2020
Node centrality	Average node degree	36.28	39.40	40.72	45.78	45.25	47.53	46.25	47.55	46.95
	Out-degree centralization	67.20%	64.00%	62.54%	58.66%	59.37%	56.82%	57.72%	56.08%	56.42%
	In-degree centralization	35.16%	37.08%	36.90%	35.59%	37.57%	40.15%	42.33%	36.85%	37.19%
Network connectivity	Network density	0.3769	0.4093	0.4274	0.472	0.4707	0.4924	0.4858	0.5084	0.5158
	Weighted clustering coefficient	0.499	0.519	0.533	0.560	0.557	0.574	0.569	0.584	0.586
	Average characteristic path length	1.539	1.519	1.501	1.471	1.465	1.453	1.455	1.431	1.419

Source: Hu et al. (2022)

As illustrated in **Table 2** the average node degree, which represents the average country trading partner from 2001 to 2020, has constantly increased reaching an average of 47 trade routes for each node of the network. Comparing the actual value to the past 36 trade partners per unit, an increase of 10 units reflects the increase in the total country involved in the international medical device trade. Alongside these statistics, the network density has risen by almost 0.2 in 10 years. As depicted in **Table 2** from 0.3769 in 2001 this coefficient reached over 0.5158, this growth describes the close relationship between trading partners in the industry which reflects the community's theory, cited above. Contributing to this aspect is also the weighted clustering coefficient which solidly remains above 0.5 for all ten years past. A notable difference displayed in **Table 2** is between out-degree centralization and in-

degree centralization. Even if out-degree centralization decreased from its peak value reached in 2001 of 67.20% to 56.42% in 2020 the distribution remains heavily uneven on all the temporal lines analysed. At the same time, the path length is the only parameter in the pool which constantly decreased reaching the lowest value in 2020 at 1.419, this data reflects that the number of intermediate countries reaching the network has decreased and direct import or export has increased due to the development of trade route and areal influence of the biggest player. The trend is also supported by a low degree of betweenness centrality showing how intermediate in general are weaker in the network and a high degree of closeness centrality which means that all relations between the countries involved are stronger and held together by the big exporters at the centre of the web (Hu et al., 2022).

To sum up, from an out-strength perspective (export capabilities), nowadays the major exporters are the US, Germany, Netherlands and China. Especially China represents one of the countries that was able to move forward in the rank, given the fact that in 2001 was not even mentioned in the top 10. On the contrary through the analyzed timeline, Japan and France lost a few positions. In terms of in-strength (import capabilities) the top 5 countries remain the US, Germany, Netherlands, Japan and China, again the path of China is remarkable **(Table 1)** (Hu et al., 2022).

2.4.1 Most influential countries in the international medical device market trade

As cited in the environmental analysis during the COVID-19 pandemic, 54 countries have imposed export restrictions to protect the domestic healthcare system. The data collected implementing the LT model by Bai et al. (2022) are displayed in **Table 3**. **Table 3** results are described by the avalanche ratio and the iterative count; this value describes how fast the influence will spread through the network.

Table 3: Most influential countries in the international medical device market trade

Top 10 seed countries in 2020 with the threshold set to 0.1, 0.3, 0.5 and 0.7.

Rank	$\gamma = 0.1$			$\gamma = 0.3$		
	Country	Avalanched ratio	Iterative count	Country	Avalanched ratio	Iterative count
1	US	0.98	4	Germany	0.98	5
2	Germany	0.98	5	US	0.98	5
3	Netherlands	0.98	5	Netherlands	0.98	6
4	Sweden	0.98	5	China	0.98	6
5	Belgium	0.98	6	Sweden	0.24	5
6	Italy	0.98	6	Denmark	0.24	6
7	China	0.98	6	UK	0.19	5
8	Denmark	0.98	6	Belgium	0.18	5
9	Israel	0.98	7	Italy	0.11	4
10	UK	0.24	4	India	0.07	2
Rank	$\gamma = 0.5$			$\gamma = 0.7$		
	Country	Avalanched ratio	Iterative count	Country	Avalanched ratio	Iterative count
1	Germany	0.98	7	US	0.22	3
2	US	0.98	10	Belgium	0.08	4
3	Belgium	0.09	4	India	0.05	2
4	UK	0.08	3	South Africa	0.03	2
5	India	0.05	2	Netherlands	0.03	2
6	Netherlands	0.04	2	Germany	0.03	2
7	Italy	0.04	3	Estonia	0.03	2
8	South Africa	0.03	2	Italy	0.02	2
9	Estonia	0.03	2	UK	0.01	2
10	Sweden	0.03	4	Spain/Denmark	0.01	2

Source: Bai et al. (2022)

The influence that a medical device exporting country has on its importing partners has two characteristics: breadth and depth. Greater breadth means that the influence of that country will cover a larger area with a more or less severe impact on the affected countries, which will therefore be large in number. Conversely, a country whose depth of influence is high at the expense of breadth means that it will have a profound influence on its partner countries. With these concepts in mind, interesting conclusions can be drawn by looking at the results obtained at different levels of threshold variation. As cited, big exporters occupy the majority of the rank positions in the net, namely the US, China, Germany and the Netherlands. All the cited countries not only have a strict relationship between them but also are well connected with a large number of other nodes in the network, therefore a restriction on their exports, as expected, has an impact on the whole system. For instance, an export restriction of 20% in the US leads to 98% of all countries being avalanched relatively quickly since except for the table with the threshold set at 0.5 the iterative count of the US does not exceed 0.5. **Table 3** also ranks two major importers of the trade network: China and India and is interesting to notice that they also have a great dynamic impact on the export market, however, they interact in different ways. Indeed, China's influence on the market has more breadth than depth rather than India which presents the opposite feature having more depth than breadth. In conclusion, export restriction by the major player of the industry can have a measurable influence on the network but is not disruptive and remains heterogeneous, in other words evenly distributed across the network (Bai et al., 2022).

2.4.2 China role and contribution in medical device international trade

Although the data gathered in the previous section constantly depicts the same major player throughout the years, China's fast scaling of this ladder represents an exception, also during the 2020 COVID-19 pandemic, the Chinese medical device industry was able to endure not only the pressure of its domestic demand but also play a fundamental role in the fight against the virus and sustain other national healthcare systems worldwide (Hu et al., 2022).

Table 4: Overview measures of China's contribution to the medical device global trade network

Category	Measure	2001	2003	2005	2008	2010	2013	2015	2018	2020
Imports and exports	Exports	15.82	25.68	49.91	110.10	134.03	202.87	236.18	318.64	418.80
	Rank by exports	16	14	11	10	8	6	4	4	4
	Imports	14.29	21.72	28.38	45.52	64.20	103.70	114.68	163.14	161.33
	Rank by imports	10	8	10	9	6	5	4	4	4
Node degree	Out-degree	64	71	77	78	77	78	78	78	79
	Rank by out-degree	12	9	7	4	7	5	4	4	2
	In-degree	33	34	35	41	40	42	45	50	51
	Rank by in-degree	15	22	22	14	16	16	11	7	7

Source: Hu et al. (2022)

As shown by **Table 4** China's medical device export shares experienced exponential growth, in 2001 the total export output was equal to $1.582 billion, in 2020 this amount was equal to $41.880 billion. Similar growth was also experienced by the import total share, starting from a value in 2001 of around $14.89 increased to $16.133 billion in 2020. It is interesting to notice that even if both statistics have simultaneously grown the difference between the two amounts is over $25 billion, describing again the distinctive features of an export-oriented market. China's commercial partners are in a total of 130 countries, and export partners are almost 55% more than import partners, accounting respectively 79 to 51 (Hu et al., 2022).

In the global medical device network mainly, the US paid the expenses of Chinese export growth resulting in an overall regression on relatively all the medical devices segments. On the other hand, Europe suffers step-backs in specific goods categories, namely patient aid, oracle care items, syringes, catheters and needles. Although the rise of Chinese exports is measurable, most exported items remain in the low and mid-end goods accounting for 30% of the total export (Brown et al 2023a). Therefore, the crowding effects created by Chinese exportation are generated by the flow of low-end products, where influential factors like the RMB appreciation in Asia and Africa combined with cheap domestic productions allowed to enhance the shares (Zhang & Chatwin, 2023).

The awareness of its strength in certain product categories has not prevented China from beginning its evolution as an exporter of high-end medical devices. Currently, made in China high-tech devices compared to highly developed countries' manufactured products have little to no competitive advantages in the market (Zhang & Chatwin, 2023), however, data shows an inward trend. For instance, diagnostic imagining instrument export increased from 1% (2001) to 11% (2021), meanwhile the share of import of the same goods significantly decreased from 34% (2001) to 15% (2021), these data shows how the Chinese productions of certain high medical complexity goods are gaining power and most likely similar path will be followed by others high developed good categories (Brown et al., 2023a).

From 2001 to 2020, China's medical device trade demonstrated a parallel evolution in import network complexity. Specifically, China's number of countries serving as import sources expanded significantly, growing from 33 distinct sources in 2001 to 51 different countries by 2020. This expansion in import sources closely mirrored the trends observed in the trade's out-degree metrics, suggesting a systematic broadening of China's global medical device procurement landscape. On the other hand, the United States, Japan, and Germany have historically dominated as primary export destinations for Chinese medical devices, and their collective market influence has been experiencing a steady and significant

decline. This trend is particularly clear when examining the market share data: these three key markets progressively reduced their proportion of China's total medical device exports from a substantial 63.91% in 2001 to a considerably smaller 34.59% by 2020. This represents a dramatic contraction of nearly 30 percentage points over two decades, indicating a profound transformation in the geographical distribution of China's medical device export landscape. In light of recent geopolitical events that have shaken international trade, these reductions come as no surprise. Eventually, this does not mean that China's importance on the international chessboard has diminished but simply relocated. These changes in the medical device market landscape for China are now divided into three major areas. North America and Europe are still there but the influence all over Asia, Africa, South America and the BRICS community has increased. (Hu et al., 2022).

Table 5: China's major export destinations over time (2001-2020)

Rank	2001	Share	2005	Share	2010	Share	2015	Share	2020	Share
1	United States of America	30.12%	United States of America	22.49%	United States of America	23.74%	United States of America	24.26%	United States of America	22.65%
2	Japan	28.90%	Japan	18.32%	Japan	11.65%	Japan	8.83%	Germany	6.34%
3	Germany	4.89%	Germany	6.25%	Germany	6.83%	Hong Kong, China	6.40%	Hong Kong, China	5.91%
4	Hong Kong, China	4.46%	Singapore	4.61%	Hong Kong, China	4.44%	Germany	6.11%	Japan	5.59%
5	United Kingdom	4.18%	Hong Kong, China	4.18%	Netherlands	3.39%	South Korea	3.11%	United Kingdom	3.82%
6	Netherlands	3.14%	Netherlands	3.22%	United Kingdom	2.86%	Netherlands	3.00%	South Korea	3.78%
7	Singapore	3.11%	South Korea	2.51%	India	2.28%	United Kingdom	2.96%	Hungary	2.91%
8	France	1.57%	United Kingdom	1.95%	Russia	2.25%	India	2.82%	Netherlands	2.87%
9	Italy	1.44%	Russia	1.92%	France	2.23%	Singapore	2.53%	Russia	2.56%
10	India	1.28%	Ireland	1.64%	Singapore	2.18%	Australia	1.95%	Brazil	2.42%
Total		83.09%		67.08%		61.85%		61.98%		58.86%

Source: Hu et al. (2022)

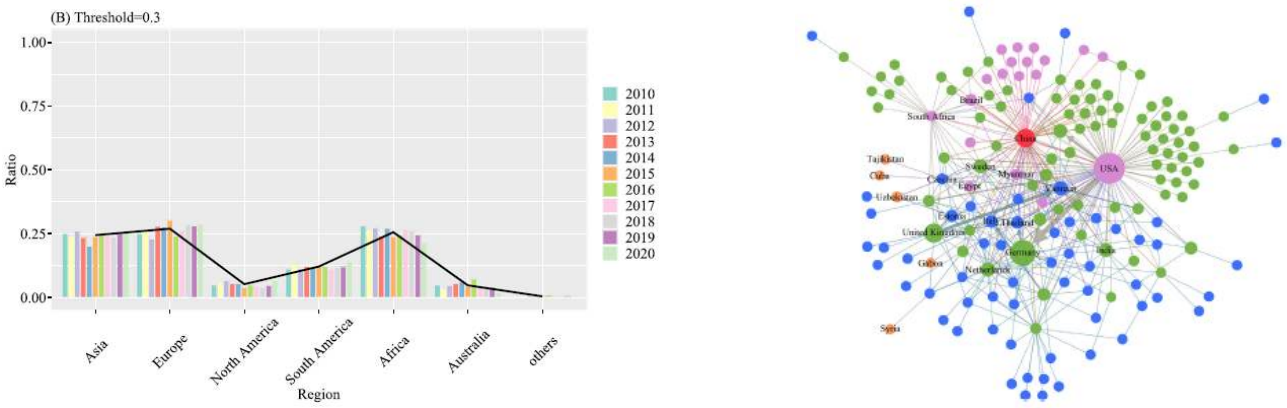
As shown by the rank under the 2020 column in **Table 5,** the majority of the listed countries are part of the Asian group with the addition of Russia and Brazil, which comes from the BRICS.

On the other hand, China's need for imports is related to the high-end medical devices demand. Some major imports come from Europe, where the UK, Germany, Netherlands and Switzerland shares ranked up. Hong Kong followed by Singapore, are by far the most important importer in the Asean area, of course from North America the US stands out as the major player. To sum up, the cited country accounts for almost 80% of the entire imported medical devices in China (Hu et al., 2022).

In conclusion, China has been a node in the medical devices export net since 2001 and truly was the only country able to scale up its economy better than any other country, becoming nowadays a crucial exporter and importer in the world (Hu et al., 2022).

Having so far presented China's role in the global medical device network with a static approach, **Fig. 8** provides a dynamic overview of the influence generated in the network.

Figure 8: Chinese influence propagation model



Source: Bai et al. (2022)

Referring to the methodology explained in **section 2.1**, as a case study, the threshold value equal to 0.3 has been selected to ensure a balanced and plausible analysis. At the range of 0.3, as shown in **Fig. 8**, the Chinese impact on the network is consistent which shows the great breadth of its influence especially at a low threshold degree. On the other hand, in 2016 and 2020 the Chinese influence in Europe and the USA deeply decreased. The cause of this fall is attributable to the already cited unpredictable event that struck the global market during this period. This shows how a reduction in Chinese exports hardly influences countries with a high anti-risk capacity in standard conditions, this feature is highlighted by the fact that the major areas of influence of China are Africa and Asia where are located less developed countries. However, the second picture which displays the propagation wave is notable how the US is one of the first countries influenced by an export reduction together with some African and Asian nations. Since China is primarily an exporter of low-end medical devices in huge quantities, a reduction in these exports generates profound pressure on one of the world's largest healthcare systems (US), creating an avalanched effect that spreads to other large nations in the network, such as Germany and UK. This observation demonstrates how some countries that are not even directly connected are still influenced by some crucial countries whose influence propagates through intermediate countries. These results prove the LT model theory where a country with a greater impact than China like the US, in this chain connection has significantly less influence than China. (Bai et al., 2022).

The interdependence index (now referring to the last methodology explained in **section 2.1**) depicts a coherent scenario with all the already cited information. From 2001 to 2020, China has bounded a gradually stronger interdependence on that highly developed economy, whose main role in the industry is the production of high-end medical devices, namely the US (interdependence index 0.9818, 2020), Japan (interdependence index 0.8744, 2020) France (interdependence index 0.9818, 2020) and Hong Kong (interdependence index 0.7867, 2020), this indicates that China's need to import this type of device from these countries has not varied, but the fact that the index is almost equal to 1 shows that these countries are also largely dependent on Chinese exports. Despite the listed country overall, the interdependence relationship has grown, reflecting the prominent Chinese influence in the industry. Little to null is the one-way dependent relationship however, it is worth noticing how within the lowest interdependence index there are Russia (interdependence index 0.0225, 2020) and Brazil (interdependence index 0.0338, 2020) this time reflecting the leading role of China in the BRICS community, at least in the medical device segment (Hu et al., 2022).

2.5 Areal insight USA, Europe, APAC

2.5.1 USA medical device market

North American population healthcare conditions are the most influential market driver for the forecasted steep growth of the American medical device market net value. To date, the total net value is estimated at $169.51 billion but experts predict the industry will reach a total market value of $328.65 in 2034. (Biospace, 2024).

As documented by the American Heart Association the percentage of cardiological disease is on the rise, fellow institutions assure similar trends for oncological and diabetes cases. This clinical condition requires the American healthcare industry to invest in the development of high-end medical devices. These factors, combined with general attention to neurological disorders, arising after the COVID-19 pandemic, result in the growth of healthcare expenditures and are reflected in the data (Biospace, 2024).

Therefore, from the current state, the market is expected to rise at a CAGR rate of 6.2% till 2024 (Statista, 2024). The United States is also the most profitable area in R&D of high-end and smart devices, with almost 7% of the total GDP invested every year in healthcare development. Investment in new technologies since 2007 has had a share growth rate of 4.5% and till 2016 the amount of patents deposited by the U.S medical device market was undisputed. Given the following data as an example, in the same year in Europe, the new patents emitted for medical devices by European entities were equal

to 41% (5,023 submissions), at the same time only the U.S enterprises and start-ups submitted 38% of the total new submission in 2016 in the same area (Hospodkova et al., 2018).

The key players operating in the North American region are 5 companies. The richest is the giant Johnson & Johnson involved in the commercialisation of advanced surgical systems and instruments for bio-surgery operation, producing an annual revenue in 2018 of $27.3 billion. The second contributor is General Electric, which stands at $19.7 billion in revenue and is involved in the promising production of imaging diagnosis systems such as X-ray instruments. In descending order by sales amount, there are Baxter International and Stryker Corporation. The latter manufacturers focus their production on patient monitoring, recovery, and intervention for acute and chronic diseases or emergency treatment. The fifth company, Becton Dickinson & Co., specializes in the development of surgical instruments, molecular diagnostics, microbiology solutions, infusion therapy, and anaesthesia instrument production. In 2018 there were total sales equal to S$15.9 billion (Hospodkova et al., 2018).

From a trade network perspective, the United States has a stable influence on the market, particularly under conditions of low anti-risk capacity. For a decade (2010 to 2020), the U.S. influence reach remained steady. Its impact spreads to multiple regions, including Europe, Asia, and Africa, with Europe being the most consistently affected. The propagation of the U.S.'s influence is primarily driven by direct trade relationships, as evidenced by the high number of avalanched countries that are direct trading partners. Germany, which represents a critical node in the global medical device trade network, is one the first countries to be affected early in the propagation process, however, is worth noticing how doesn't play the role of intermediator and does not create any serious avalanched effect. The U.S.'s influence is therefore characterized by direct, stable connections rather than reliance on secondary trading partners, highlighting its central role in shaping international medical device trade dynamics (Bai et al., 2022).

To sum up, although the forecast of the U.S. market is overall positive, its primacy will be undermined by emerging markets, most likely China, India and Brazil, where most of the world's population will be located shortly. In addition, financial, and regulatory challenges and inefficient reimbursement systems will gradually decrease the appeal of this region for foreign investors and slow the growth of the American domestic medical device market (Awasthi & Stanick, 2022).

2.5.2 Europe medical device market

Europe is the second most important region in the medical devices landscape, holding about 30% of the global market with a net value of $110 billion. It is the home of 27,000 manufacturers, employing

almost 675,000 people. Those companies generate market shares of a variable of $130 to $145 billion (Hospodkova et al., 2018).

A few tycoon companies lead the market, namely Medtronic in Ireland involved in the production of surgical instruments with an annual value of $30 billion, which is worth noticing surpasses the annual revenue of the biggest US. Company. Germans Siemens Healthcare which produces imaging devices and Fresenius whose business is almost vertical in the production of medical technologies for dialysis, both companies produce a similar revenue between $16 and $20 billion. However, the strongest feature of the European medical device market is the great number of small and medium enterprises, basically start-ups, that invest in the development of new technology, this attention to the R&D of the sector has produced 7.7% of total new patents in the global medical device industry. In Europe, 10.4 % of the total GDP is invested in the healthcare sector but it is crucial to consider that this number varies based on the given country (Hospodkova et al., 2018).

To simplify the descriptive analysis of this area the following paragraphs will take a look at the so-called EU5, the five most influential economies in the region: France, Germany, Italy, Spain and the UK, even if Great Britain is not anymore, a formerly European member is still part of the macroeconomic region.

The richest countries in the medical device sector are Germany and France, between the two, German sales revenue accounts for $90 billion in 2022, capturing 67% of the European MedTech market share, on the other hand, in the same year the French market produced a net value of $25 billion. Different market share numbers are attributable to heterogeneous variables, however, the biggest difference between these two nations is in the market drivers. The geriatric phenomenon of the ageing population largely affects the French rather than the Germans. The German market instead is moving forward with the government's investment in the future trend of medical devices, such as digital health, biomedical devices and diagnostic and imaging technologies (Awasthi & Stanick, 2022).

In the south of Europe, Italy's medical device sector size almost doubled Spain's ($6 billion) counterparts, with a total revenue of $14 billion but a slow growth rate of 1.3%, essentially due to the rehabilitation of public debt. The public debt diverts the resources originally intended for the sector. Is also necessary to mention that even if Italy's healthcare industry is characterized by substantial domestic production, depends on a large scale of imports (Awasthi & Stanick, 2022).

Such a low growth rate should not come as a surprise given that the average growth forecast is only 4%, this is basically due to the huge limitations imposed by the European Union regulatory framework, which disincentivizes the development of domestic research and the amount of foreign investment. (Awasthi & Stanick, 2022).

On the contrary, Eastern Europe has emerged as an attractive destination for Western European MedTech companies. Streamlined regulatory procedures and straight access to cost-effective and qualified labour forces made up the two main competitive advantages of the micro-section of the Europe area. The sector has further benefited from the rise of private healthcare facilities, which have introduced new revenue opportunities in the medical device market (Awasthi & Stanick, 2022).

Considered as a whole, Europe is a pivotal player in the industry, and its powerful members have a major influence from a trade network perspective. For instance, Germany consistently held a significant position within the industry with a broad and deep influence across Asia, Europe, and, to a lesser extent, Africa. Sweden exhibited substantial influence in Asia, surpassing the depth of its impact on Africa, where Sweden's influence is bigger than on its European neighbour. On the other hand, the United Kingdom and Belgium had a deeper influence within the region. However, their influence in Asia lacked depth. The UK also demonstrated unique influence dynamics in South America, where its impact was more pronounced than that of Belgium but due to Brexit, it lost influence in Europe and on the global trade network. Looking closely at the influence propagation, Germany and Sweden have a direct impact on China and the US, which consequently play the role of intermediate spreading all over the influence of the original European countries (Bai et al., 2022).

2.5.3 APAC medical device market

The Asia Pacific region (APAC) is the largest among the three areas covered in this section. It can be geographically divided into 60 different countries. For the most part, they are small and middle-income nations forecasted to become the biggest destinations for exporting medical devices due to their unique characteristics such as Indonesia, Philippines, Thailand, Malaysia and Bangladesh. To date, the region is dominated by affirmed highly developed economies and healthcare systems namely Australia, Japan, South Korea, Singapore and Hong Kong, however, within these groups, there are the future major actors of the medical device industry represented by China and India (Sapkota et al., 2022).

Except for the latter countries, which are settled to gain a pivotal role in the industry on a global level, most of those nations are net importers, i.e. their medical device sector depends on importing. A hint to understand the high dependency levels of this developing NHS is given by the Vietnam situation where data suggests that 90% of the medical devices in the country are all imported (Jakovljevic et al., 2021).

APAC's richest region is the south-east coastal section, where there is located strong industrial economy with a steady growth of middle-class income and expenditure potential in healthcare facilities and goods. Experts forecast an increase of middle-class APAC citizens of 65% by the end of 2030 (Jakovljevic et al., 2021).

Each country's heterogeneous features, but the economic potential of the area is attributable to a common denominator. All these nations share a high quantity of raw materials, relatively high potential in technological development, and a great number of coachable labour force which contribute to building solid market drivers for the industry (Sapkota et al., 2022). This market condition makes the APAC nations the perfect targets for FDI. The data shows how in a five-year cycle from 2014 to 2018 the growth rate of foreign investment in Asia was around 44%. This amount is more than double the FDI compared to the US, which accounts for 17.8%. Moreover, the medical device market growth in the region is driven by some unique trends, for example, Thailand and Korea are famous destinations for the so-called medical tourism. Therefore, plans for investments in hospital infrastructures are settled to boost the sector (Jakovljevic et al., 2021).

In addition, the strongest asset of the APAC region is its demographic size, the Asian Pacific countries already host over 60% of the world population accounting for 4.5 billion people, this data is even more influential if it is linked with the ageing population growth rate in the area. As mentioned, this third demographic transition is a crucial market driver in the industry, and it acts as the trigger of other avalanched effects. Therefore, the Asia-Pacific population over 60 years old will reach 1.3 billion in 2050, representing a huge potential market for medical device worldwide manufacturers (UNFPA, 2024).

These environmental patterns described in the forehead paragraphs are reflected in the following data displayed in **Fig. 9**.

Figure 9: Medical device market size compared by region

Source: Jakovljevic et al. (2021)

Fig. 9 compares the main area highlighted in this section and shows how APAC, during the 2017-2023 period, has experienced the biggest growth in terms of net value, with a total growth of $42 billion

reaching $137 billion in 2023. After the hit of this unpredictable and disruptive event among all the Medtech market in the world the APAC region industry growth with an average 9% CAGR rate to reach $150 billion, after only 14 months since the spread of the virus and consequently shut down of the world economy, (Jakovljevic et al., 2021). Therefore, the industry is set to reach a net value of $800 billion by 2030 (Sapkota et al. 2022).

While the growth of these countries is irrefutable, as the data show, many of them still depend on imports from within and outside major industries. The main barriers slowing down growth are the technology gap with more developed countries that is difficult to bridge, the lack of up-to-date regulatory systems that allow for the implementation of new technology, and a general mistrust of consumers themselves who continue to prefer foreign medical devices. The situation differs for the big players already established and those that will scale up, likely China. Their growth is inevitable, and technological evolution is evident (Sapkota et al., 2022).

Shifting towards a particular perspective, the following paragraphs describe the main protagonists of the APAC area.

- **India and Bangladesh**

India is already within the top 20 biggest medical device markets in the world (Awasthi & Stanick, 2022). However, there is robust evidence to suggest that India is settled to quickly rank up this ladder reaching the fifth position by 2030 (Sapkota et al., 2022). The industry is characterized by a well-mixed environment of giant multinationals and small-medium enterprises, these realities are supported by government policies, namely: “Ayushman Bharat” (health insurance scheme), “Startup India” (support for startup businesses) and “Make in India” (Awasthi & Stanick, 2022). In addition, both companies’ categories are essentially driven by a vast amount of FDI, since the Indian government have completely opened the sector to foreign capitals, thriving the technology development and revenue. The current value of the industry is around $11 billion; however, it is expected to reach $50 billion by the end of 2025 (Lalwani & Suvarna, 2021).

On the other hand, Bangladesh compared to India is a small-income country which relies mostly on imports, which accounts for $400 million during 2019-2020. Manufacturing accounts for only 5-7% of the over 4,000 devices and equipment in use, generating an annual net revenue of $60 million. This means that in the trade network, Bangladesh will mostly represent an opportunity as an import partner especially for a big neighbour like India (Sapkota et al., 2022).

The driving elements for both countries are the maturing populace, expanding social insurance consumption, and innovation progression (Lalwani & Suvarna, 2021).

- **Singapore and Hong Kong**

Singapore represents a renowned global hub for the healthcare industry, especially for the biotech pharmaceutical sector. It is the home of over 1.5 times more pharmaceutical companies than China, Hong Kong, and Japan combined. Nonetheless, the country represents a pioneer in the technological development of medical devices, hosting 11% of the total start-ups in the region. This major presence of innovators is attributable to a favourable regulatory framework for technology development and foreign investment. Only In 2020 in Singapore around 18.000 new IVDs were registered (Jakovljevic et al., 2021).

Another valuable data which demonstrates the high technological level of the Singaporean healthcare system is that 82% of the professionals utilize a digital health technology instrument to monitor and carry out medical procedures. In conclusion, to give a hint of the size in 2020 the net revenue of the Medtech sector was around US$1 billion with an annual growth rate of 8.8%, on the other hand, the imports in 2019 were estimated at around $4.2 billion (Sapkota et al., 2022).

When it comes to Hong Kong the market drivers are essentially the same as in Singapore. The friendly environment for innovation allows the development of new technologies, especially in the field of IVD, which is the biggest market in the city with a net value of $130 billion in 2023 (Kalorama Information, 2023). This stake represents more than half of the total medical device transactions accounting for $2.037 billion in the previous year (International Trade Agency, 2023).

Both medical device market economies depend on the IVD domestic production for the characteristics of this goods category. IVD medical devices are for the most part relatively small products, which means that they do not necessarily need a vast number of raw materials. From a logistic perspective, the supply chain is relatively short, and there is no need for an extensive implant site for production. Moreover, the value of these goods is linked to their technological complexity, the more the IVD goods are advanced the more advantages have on the global market, therefore, for instance, the Hong Kong government incentives manufacturers of high-level IVD to apply national regulatory framework to facilitate the access to the public procurement system and enhance the market of the goods and the total revenue of the industry.

- **Japan and South Korea**

Japan is categorized as a high-income country and its well-developed healthcare industry is ranked high, holding a total share of 6.6% of the global medical device market (Awasthi & Stanick 2022). Japan has

one of the most stable and well-structured healthcare and reimbursement systems in the world, owning the highest medical insurance expenditure around 83.6%. On top of that, the main industry market driver is medical device innovation and development. Japan registered around 8% of the total healthcare start-ups in Asia, these entities develop and produce high-end medical solutions and robotics medical devices, thanks to experienced and innovative engineering know-how (Jakovljevic et al., 2021). It is worth broadening the analyses around the new robotic solutions developed in the country for monitoring and treating diseases purposes. This development direction is related to the large elderly population present in Japan; these needs combined with a gradual weakening of the traditional family caregiving process enhanced the demand for home-based monitor robotics. This particular sector in Asia but especially in Japan from 2018 to 2023 experienced an astonishing growth rate of 12.9% (Jakovljevic et al., 2021). Backing up to a general perspective, the total transition revenue was equal to $34 billion by 2022 and is expected to reach $74.7 billion by 2025 (Sapkota et al., 2022). However, internal competition and the absence of direct approval of the CE mark and FDA-approved products in Japan limit revenue growth to a moderate 3% (Awasthi & Stanick, 2022).

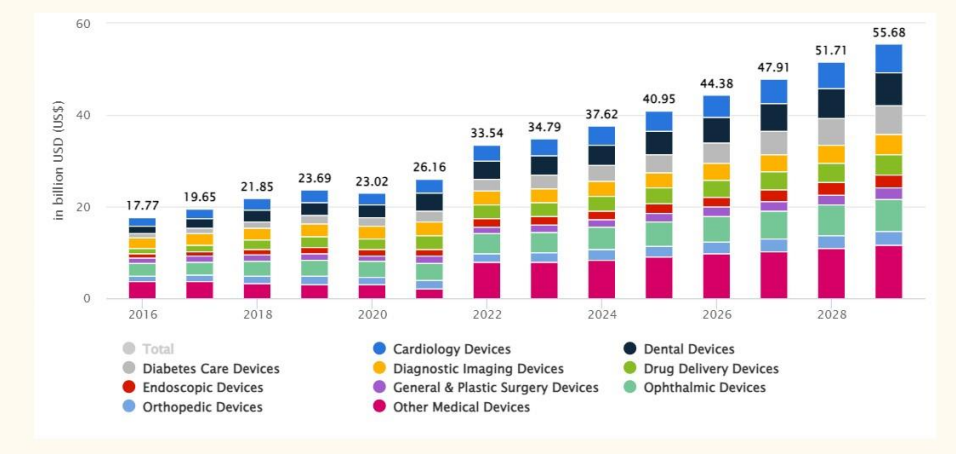
South Korea is one of the high-income countries in the APAC area, with similar environmental and market drivers' characteristics as Japan but in a smaller dimension. The South Korean medical device market is projected to grow significantly, with a compound annual growth rate of 10.9% in USD terms from 2023 to 2028, potentially reaching $12.3 billion by 2028 (Statista, 2024). The most notable aspect of this country is the high investment in the hospital sector to enhance medical tourism. Moreover, surgical devices saw a high level of employment attributable to the cultural attention to surgical operations. In Asia, where the youngest female population is particularly sensitive to this aspect this sector is expected to grow with a 4.6% CAGR till 2026 (Jakovljevic et al., 2021).

- **China**

According to the International Monetary Fund, China is the second-largest economy in the world but is still classified as a middle-income nation. The large room for development in GDP will consecutively reflect itself in the expected growth of the domestic medical device industry (Jakovljevic et al., 2021). To date, the Chinese medical market industry's net value accounts for $37.61 billion, however among all, is forecasted to grow with the highest CAGR of 8.16% (Statista, 2024) and it occupies slightly more than 10% of the global market share (Hospodkova et al., 2018), in 2028 is forecasted to peak with a market share equal to $55.67 billion **(Fig. 10)** (Statista, 2024). Despite the dimension of the country's economy, the high-end medical device industry still depends on imports, with 80% of technologically advanced

goods imported (Awasthi & Stanick, 2022), the main suppliers are the US, Japan and Germany (Hospodkova et al., 2018). Historically, Chinese domestic production is mainly focused on low-end medical devices which feature a relatively low technology core, namely Personal Medical Devices (PMD), IVD for basic diagnosing purposes, surgical masks or syringes and China's medical infrastructure demand for high-end medical devices is supplied by foreign manufacturers (Cheong et al., 2020).

Figure 10: Forecast of China's medical device market and product categories size (2016-2024)



Source: Statista (2024)

Fig. 10 displays an interesting insight into the medical device market evolution from 2016 to 2029. It is notable how the general growth trend was only interrupted in 2020 with a lower net revenue ($23.02 billion) compared to the previous year ($23.69 billion) mainly attributed to the unpredictable explosion of the COVID-19 pandemic (Statista, 2024). It can be affirmed with solid ground that China played a crucial role during the pandemic providing on a global scale anti-covid tests and surgical masks for protection, but at the same time domestically suffered a deep shortage of high-end respiratory medical apparatus to sustain a high number of elderly COVID-19 patients. This event further highlighted the need for evolution in this aspect (Zhang & Rao, 2021). In reality, through a diversified spectre of actions, which comprehend government intervention, and the specific market drives the shift towards high-end medical device production is already taking place and is reflected by the data in **Fig. 10**. Despite the purple section named other medical devices, which contain the majority of low-end goods, a key segment of the industry characterized by a high technology complexity levels core such as cardiology devices, diagnostic imaging devices, diabetes care devices and dental devices are on the rise and are forecast to gradually occupied a bigger portion of the entire market share (Statista, 2024). The positive

trend in this specific segment is intertwined with the medical conditions of the Chinese population, as cited multiple times in the thesis, this represents a crucial market driver.

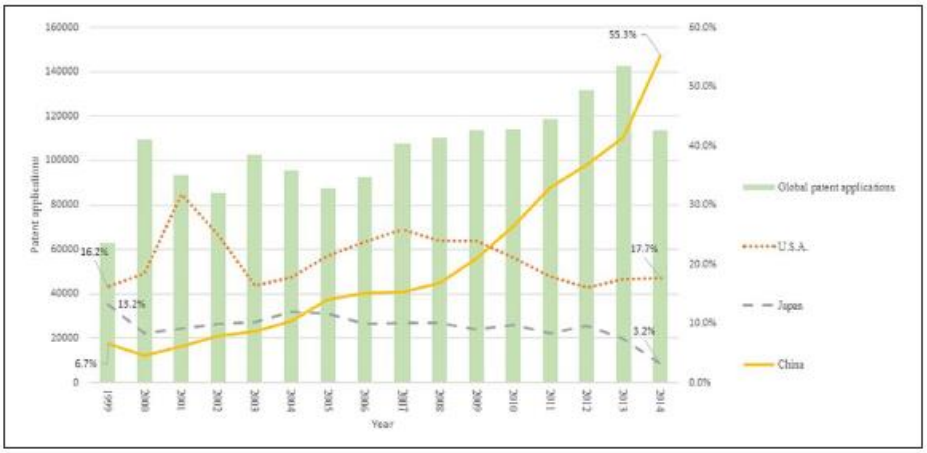
China is probably the most sensitive and exposed country to the geriatric condition of ageing of the world population (Boyer et al., 2015). This trend will create an avalanched effect influencing several segments of the domestic medical device industry starting from PMD and remote healthcare monitoring instruments (Sapkota et al., 2022), moreover, non-communicable diseases (NDC), which are already affecting a vast portion of the Chinese society accounting for 290 million people will also represent an opportunity for the industry stakeholder to pave the way of a new streamline of revenues linked to relative interested medical devices (Jakovljevic et al., 2021). Moreover, since this section of the population is statistically weak and prone to injuries, the most common diseases and related medical goods implemented for their prevention, diagnosis, and treatment are settled to raise revenues. For instance, a significant proportion occupied by cardiology devices can be to a certain extent attributable to almost 270 million people in China with diagnosed hypertension (Li et al., 2020). In addition, the rapid spread of the urban lifestyle, unhealthy diet and sedentary life habits led to an increase in lifestyle-related diseases. For instance, since 2019 over 200 million Chinese citizens suffer from obesity, this condition is often aggravated with diabetes, which has been already diagnosed in 92.4 million people or fatty liver condition which affected 120 million Chinese, all these patients need specific treatment and there are enough hints to affirm with solid ground that medical devices to treat obesity and diabetes will lead a rapid growth of the segment in the short term (Wang et al., 2019) Therefore, the condition affecting the health of the public is again confirmed as a valuable market driver.

As mentioned at the start of this section, China is considered a middle-income country, however, the GDP in conjunction with all the other economic aspects is on the rise. This growing dimension is reflected in an increased health expenditure by the citizens reaching 50% in 2020, compared to the public expenditure which accounts for slightly more than 55% in the same year, which results in a boost to the medical device industry but on the other hand, a vast and consistent out-of-pocket (private citizens spending) expenditure in the healthcare system could be a symptom of a weak reimbursement and healthcare insurance system. In the Chinese environment, this assumption to a certain extent is true. However, a detailed presentation is done in a more appropriate section further in the thesis (Jakovljevic et al., 2021).

Besides the clinical condition-related market drivers, the Chinese medical device industry is expected to play a leading role in medical innovation with the long-term ambition of solidifying its influence in some specific areas and becoming a worldwide exporter. This shift in the role of China in the network

will take time and significant economic effort however a valid measurable variable to draw an overview of the progress through time is counting the total new patents issued in a given period **(Fig. 11)**.

Figure 11: Comparison between global and Chinese patent applications (1999-2014)



Source: Cheong et al. (2020)

Despite the relatively old data gathered in Fig. 11, the graphic still gives valid hints to understand the Chinese effort dimension to enhance their R&D activities. Overall, Chinese patent applications experienced a constant scaling trend with a stable growth rate of 3.77%, exceptionally accelerated in 2009 to a 6.7% rate which led to a total successfully issued new patents of 1.678.339 among all the period examined. Shifting towards a particular perspective, the field where the most investments were and till today are made are three. The first one is diagnosing, surgery and identification medical devices accounting for 36%, followed by implantable medical devices at 18% and with a similar percentage of 16% the third place is occupied by interventional medical devices (Cheong et al., 2020). Despite the crucial role played by R&D in the industry, the significant growth experienced by some specific goods categories is attributable to their presence or absence on the national procurement list, a unique government mechanism that is widely presented in a dedicated section.

To ensure a correct understanding of this section, it is important to keep in mind the huge territory extension of this country, therefore all data presented here are from a general perspective, since between a coastal city and a rural village the data divergence can be significant, a more detailed description is presented further in the thesis.

Not far in the past, the domestic landscape was occupied by several SMEs which operated on a regional level mostly as producers of low-end mid-end goods categories. These entities didn't have either economic strength or technical knowledge to expand themselves or scale their operations (Cheong et

al., 2020) and occupied almost 80% of the entire manufacturer's population (Hospodkova et al., 2018). This condition was also attributable to the fact that the high-end market was monopolized by foreign distributors, leading to patent barriers and price profiteering strategy, consistently increasing the cost of this kind of goods (Zhang & Rao, 2021).

The intervention of government policies and tax concessions combined with strategic inner M&A operations created a highly competitive domestic market dominated by a few giant companies (Cheong et al. 2020). Nowadays in China, there are around 18000 different manufacturers (Zhang & Rao, 2021), how these companies interact with government institutions and the market is unique on the global scene, so an entire section of this thesis has been dedicated to this dynamic, where some of the points mentioned in the above paragraphs will be taken up and explored to understand how the Chinese medical device industry works from the inside and further highlight its role in the global medical device industry.

Chapter 3: Chinese Government's policies for the domestic medical device market

3.1 China’s healthcare system

The Chinese National Medical Security System (国家卫生健康委员会) is a multilevel institutional arrangement with the ultimate objective of reducing citizen's economic and social burdens regarding medical diagnosing and treatment of diseases and it is the largest institution of this kind in the world (Yi, 2020). This record is attributable to the large Chinese population accounting for 1.48 billion individuals (2024) roughly divided into 66% of the population living in urban areas and 34% living in rural villages (National Bureau Statistics of China, 2024). A large population entails a high public health risk and a wide spread of harmful diseases that generate challenges and economic pressure on the healthcare system. Throughout the thesis, we have repeated multiple times the major future challenges for the health of the Chinese population. Hence, the threats are identified in two trends. The third demographic transition and NCDs. On one hand, the elderly population over 65 years old counts over 220000 people and their dependency ratio is relatively low (22.57%) (Chen, 2024), raising pressure on household care and sanitary personnel, which is already lacking (Zhang & Rao, 2021). On the other hand, NCDs are by far the fearest threat to public health, accounting for 90% of total deceases (World Health Organization, 2024).

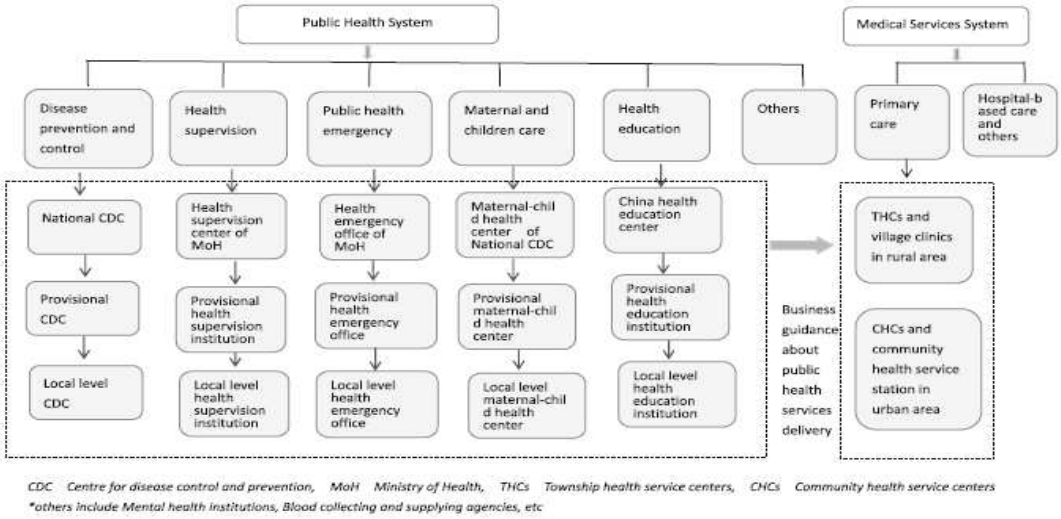
The national system's core financial sustain is basic medical Insurance assisted by medical aid, commercial health insurance, charitable donations, and medical mutual aid activities which cover the role of supplementary services. Currently, the system covers almost 99% of the Chinese population and government funding is increasing yearly. The government health expenditure in the last five years had a generally positive trend reasonably peaking during the COVID-19 pandemic (30.40%), levelling out with 2024 at a fair 26.6%, coupled with social and personal expenditure, this will total 7.19% of the country's GDP by 2024. The value compared to other countries is quite low, for instance even in the BRICs group, Russia and Brazil surpass China (Wang et al., 2019), but it is rationally proportionate to Chinese citizens' average GDP per capita US$12.614,06 (National Bureau Statistics of China, 2024).

The system covers two groups of people and is divided as follows: UEBMI Urban Employer Basic Medical Insurance (城镇职工基本医疗保险) and Residents Basic Medical Insurance RBMI (城乡居民基本医疗保险). Respectively they include around 378 million and 1.040 billion people (National Bureau Statistics of China, 2024) this significant difference in membership is mainly because, the latter, also includes all individuals still holding a rural and non-urban hukou (户口). Before 2016 this huge segment of the Chinese population owned a specific public health coverage. Since that year it has been unified into single coverage, to reduce the inequality of access to basic health services that still affects the country's

most rural areas (Xie, Qin & Gao, 2020).

Alongside the National Medical Security System Chinese citizens can benefit from the Public Health System (中国公共卫生体) (Xie, Qin & Gao, 2020). The system has historically been able to adapt and meet their health protection needs. Throughout history, this system has experienced four stages. During the initial stage of Prevention (1949-1978) the guiding principle was the spread reduction of pathologies related to poor health conditions, namely malaria and tuberculosis. Consequently, the system shifted towards an era where the main attention was medical treatment, boosted by a strong market and revenue-centred policies (1978-2003). Sooner the first unpredictable pandemic of Sars motivated the institutions to revolutionize their commitment to preserving public health. After the second recent pandemic and successfully facing the consequences, Chinese Public Health has now focused on reducing the equity gap and enhancing the people-centred degree. The current Chinese Public Health System is structured as depicted in **Fig. 12** (Wang et al., 2019).

Figure 12: Chinese Public Health structure



Source: Wang et al. (2019)

These state superstructures gain strength and continue their development as part of a large long-term project that is also strongly supported by the current party secretary Xi Jinping, this policy is titled Health China 2030 and is presented in detail in **section 3.7.3** of this chapter (Tan, Liu & Shao, 2017).

The progress of China's public health is undeniable. The size of the system and the inequality in economic production between coastal and rural areas result in evident shortages. The common cause is insufficient per capita health expenditure, which is reflected in a relatively low number of hospitals and clinical infrastructure, these factors are combined with an inadequate number of sanitary human

resources. From a modern health digital ecosystem perspective, IT automatisation and a deeper patient healthcare database could be improved to strengthen the knowledge diffusion between medical infrastructure and government institutions (Li et al., 2020).

In China, the number of registered hospitals is equal to 9293 units (National Bureau Statistics of China, 2024). Since this medical infrastructure represents the biggest end-user in the industry, it is possible to confirm with solid grounds that an increase in quantity would benefit the industry revenues.

To face this issue, in September 2024, three major Chinese institutions: China's Ministry of Commerce, National Health Commission and National Medical Administration jointly opened key high-developed areas namely Beijing, Tianjin, Shanghai, Nanjing, Suzhou, Fuzhou, Guangzhou, Shenzhen, and Hainan to the establishment of wholly owned foreign capitals hospitals. Nonetheless, there are strict regulation compliance requirements but there is still an enormous opportunity to thrive in medical device development, and sales and stimulate the overall growth of the sector (Reuters, 2024)

3.2 Breakdown of medical device industrial clusters in China

There is concrete evidence to affirm that the Chinese government has been consistently investing in the domestic medical device sectors, with the long-term ambition to establish its home production as a leader in the international landscape. It is a common practice in the Chinese environment to identify industrial clusters located in specific zones and stimulate production and research through investment state financial support and regulatory simplifications. These industry clusters have been boosting competitive conditions for developing medical devices, such as basic science research, innovative industrial design, good manufacturing capability, convenient transportation, concentration of universities and high-level hospitals, and a mature financing system. In this paragraph, these clusters are presented.

- **Bohai Pacific Rim**

The Bejing-Tianjin Bohai Rim region is located in north-east China and its perimeter covers all the Bejing Bay Area. Probably, among all the zones of interest presented in this section is the least vertical in the medical device sector, however, it has a crucial role especially in the R&D activities (Cheong et al., 2020). The presence of the capital in the area certainly represents a pivotal advantage, since Beijing attracts a vast amount of FDI, making this zone suitable for economic cooperation. The zone is also known for its heavy and chemical industries and as a high-level education hub (Zhang, 2016).

- **Pearl River Delta**

The Pearl River Delta is positioned in southeast China and comprises Guangdong province, with nine cities, and the two SAR (Special Autonomous Regions) of Hong Kong and Macao. These latter-cited locations represent an important hub for FDI (Zhang, 2016), however, it has been several years since these two cities lost their worldwide appeal in the first decades of 2000. To date, most of the interest is attracted by the mainland, especially for medical device industry investment.

Compared to the first zone presented the Guangdong-Hong Kong Macao Greater Bay Area has been selected as a vertical industry cluster for high-end medical device development. The investment from the Chinese central government is proven by the fact that in 2020 alongside Shenzhen, Shanghai and Guangzhou governments founded two institutions for Medical Device Technical Review and Inspection Center (医疗器械技术审评检查中心) with the specific intention of enhance the production and simplify the streamline to get the market access for high-level medical goods. To give a hint of the Chinese government's effort to sustain and develop the industry, agglomerated in this area are registered respectively 3691 companies producing Class I medical devices, 2399 producing Class II medical devices and 349 producing Class III medical devices. Looking directly at the cities is notable how the most high-tech developments are conducted in Shenzhen and the majority of low-end goods are produced in Guangzhou, which economy flourished during the recent COVID-19 pandemic because became the first city in the world for PPE (Personal Protection Equipment) production and exporting. To sum up these data, from 2018 to 2021 the cluster growth rate experienced a positive trend with a CAGR equal to 16.8% (Yang, Ouyang & Wu, 2024).

- **Yangzi River Delta**

The third industrial cluster presented in this section is the Yangzi River Delta economic area, located between the previous two zones, it is the biggest in terms of regions and cities involved. The core is represented by the special municipalities of Shanghai surrounded by the regions of Anhui, Zhejiang and Jiangsu (Zhang, 2016). The region can be described as a high-tech manufacturing zone where a vast number of entities between companies and institutions produce the highest level of medical complexity degree goods among all the zones presented. This condition creates a significative comparative advantage, especially regarding the production of IVD, medical imaging devices, therapeutic devices, and polymer medical materials. This area by far produces the highest revenue in the Chinese medical device industry as reflected by the data. Shanghai only in 2021 has a net value of around 900 billion RMB with an average CAGR in 2018-2021 of 14.6%, similar to the entire Pear River Delta annual growth rate. Looking at the statistics Jiangsu province is the most productive region in the Chinese medical device domestic industry with annual revenue in 2021 of 3400 billion RMB and an estimated CAGR of around

12.5 % (Yang, Ouyang & Wu, 2024).

- **Boao Lecheng Pilot Zone**

Boao Lecheng Pilot Zone is not a conventional industrial cluster, there is no significant production of medical goods but is worth analyzing the ongoing government initiative to simplify the market access for specific medical goods in China. The free-trade zone (FTZ) island is located in the southeast ocean and has been chosen to experiment with the pre-market clinical evaluation process of medical device performance and compliance with regulation based on real-world Experience (RWE) derived from the collection of real-world Data (RWD) (Cai et al., 2023). Real-world Data are all the information collected outside of the canonical clinical trials and then converted into RWE, which is the actual information that helps to evaluate the regulatory decision of whether to let the goods access the market or not (Li et al., 2023a), indeed as cited previously in the thesis, regulatory compliance is one of the major barriers to enhance development and revenue in the industry (Cheong et al., 2020). To date, this is the first and only experimental zone of this kind in China and will open a promising future scenario not only for Chinese domestic industry but will set an example of how to implement the utilization of RWD in the medical device sector (Cai et al., 2023).

The goods to be eligible to participate in the experiment must meet specific standards, firstly they have to be foreign products and have already accessed outside markets, and then they must answer an urgent demand in China's healthcare landscape that cannot be satisfied by domestic existing production. Alongside these strict requirements, data acquisition is regulated by the National Medical Product Administration. The NMPA has established two main evaluation criteria for data quality: relevance and reliability. Relevance ensures that the data is appropriate to answer the right question and reliability where the data is valid. Together with that, the Chinese institutions established six aspects of data quality: representativeness, completeness, accuracy, authenticity and probably most importantly consistency. The two methods implemented for the collection of data are the proactive collection (prospective or retrospective and outside or inside the FTZ) from data sources such as patients local medical institutions or medical device manufacturers or the routine collection (inside the FTZ) which tracks the entire life cycle of the examined medical device during its application made by IoT devices such as intelligent wearable or Boao Lecheng Real-World Data Research Platform or “Lecheng Health” smartphone app (Li et al., 2023a). Therefore, foreign past collected data can be utilized but must comply with China’s Personal Information Protection Law (PIPL) and the given country data protection regulations (Cardilli et al., 2021).

The main challenges and concerns of this experiment are data reliability and data sharing because these

two aspects will affect data quality, along with some ethical concerns (Li et al., 2023a). Is notable how nonetheless China is investing heavily in the implementation of software, IoT and AI devices there is still a lack of an efficient communication method for data and patient databases, as already mentioned in the previous **section 3.1.** Experts forecast that a good degree of leveraging healthcare data could shortly represent a crucial market driver in the industry (Sun, 2024).

The experiment has already shown a significant success case. In 2019, the medical device called “XEN”, a glaucoma drainage tube which technically is a high-end Class III medical device was introduced in the Boao Lecheng zone and in March 2020 was approved to be utilized in the mainland. To date, the implementation of this medical device has changed the lives of almost 22 million Chinese patients, representing a major success for this Chinese government initiative (Sohu, 2021).

The initiative made the island extremely appealing for medical tourism since the treatments which implemented high technological devices are cheaper and due to shorter trials to access the Chinese market has become one of the enter main channels for foreign enterprises (China News, 2022). The broad attention to streamlining market access is also related to the ambitions of the Chinese Party to incentivise foreign enterprise localization. This practice is largely supported by the Marketing Authorization Holde (MAH) policy. The policy separates the marketing and manufacturing responsibilities; therefore, the foreign company can hold the marketing authorization and meanwhile outsource the production of the goods to a domestic manufacturer already certified, consequently cutting the time to market from a minimum of 15 months (Class III devices) to a maximum of 26 working days (Lin, 2022).

3.3 Overview of the main Chinese company involved in the industry

In this section, the biggest Chinese players in the domestic and international medical device landscape are presented in a structured table. The information in **Table 6** has been retrieved from the official companies' websites as follows: (Mindray, 2024; Yuwell, 2024; Microport, 2024; Lepu, 2024; Weigao 2024; Venus Medtech, 2024). The net sales value has been taken from (Markets Seeker, 2024), and additional information comes from the academic paper Cheong et al. (2020).

Table 6: Overview of the main Chinese company involved in the industry

Company Name	Province/City	Market segment	Business strategy	Net Sales CNY (2024)
Mindray Medical International Ltd.	Guandong, Shenzhen	Mid and high-end MDs (patient monitoring devices and ultrasound imaging systems), ranking top 3 global information monitoring brands	Localized R&D center and robust M&A campaign	38.51B CNY
Yuwell Medical Equipment & Supply Co.	Shanghai	Mid and high-end MDs (homecare devices and oxygen supply devices)	Strong marketing campaign and international brand recognition, cooperation with research institutions	8.23B CNY
Microport Scientific Corporation	Shanghai	Mid and high-end MDs (patient monitoring devices and cardiovascular instruments, e.g. coronary stent, where lead the domestic market)	Exports and consolidate core businesses	1.28B CNY
Lepu Medical Technology Co. Ltd.	Beijing	High-end cardiovascular technology (interventional cardiology devices, artificial heart valves, cardiac pacemakers, and diagnostic equipment for heart conditions), foremost provider in the field	Cooperation with the National Engineering Center of Cardiovasology, M&A campaign, expansion in third-level Chinese cities	6.32B CNY
Weigao Group.	Shandong, Weihai	Mid and low-end MDs to supply hospitals and single end-user	Widespread marketing and export, low technological complexity with high added value	1.47B CNY
Venus MedTech	Zhejiang, Hangzhou	High-end cardiovascular surgical devices, minimally invasive solution. Own the patent of VenusP Valve, the first ever chinese coronary stent commercialized on a large scale in Europe	R&D, exports and consolidate core businesses	406M CNY

Sources: Elaborated by the author

3.4 Overview of the Chinese government's policies for the domestic medical device market

The development of the Chinese medical device sector can be divided into four historical phases. From the 1960s-1970, the market experienced an initialisation phase where domestic companies limited themselves to imitating the production of low and mid-end goods. In the 1980s, an exploration stage was guided by the opening reform issued by the then-party secretary Deng Xiaoping and the first sino-foreign joint ventures. Consequently, the sector experienced steady growth (the 1990s) and since the 2000s has been in the rapid growth phase where Chinese entities started the production of self-made high-end medical goods. Besides all the situational market drivers occurring in the different stages, the most influential factor in the Chinese medical device industry landscape is the direct intervention of the government through policies, especially under the guidance of President Xi Jinping, who has made the Chinese repositioning in the global medical industry one of his missions (Cheong et al., 2020).

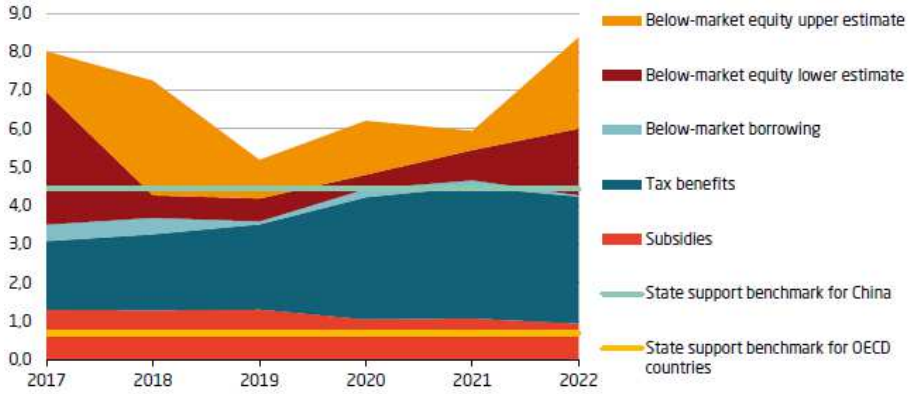
This targeted focus has deep roots and is part of a much broader programme launched in 2016 the so-called "Outlines on National Strategy for Innovation Driven Development" (国家创新驱动发展战略纲要), which aim to take down the long-standing "around the neck" issues (卡脖子问题), related to long-term development and national security which should be strengthened by the implementation of forward-looking plans for basic research (Zhang & Rao, 2021)

Medical devices have rapidly scaled up the Chinese government's technology priorities. Now the ultimate objective is to reshape the Chinese industry as a leader in the production and export of high-end medical devices, consequently reducing dependency on imports, self-reliance on the national healthcare system and enhancing technological security through restricting cross-border data transfer, especially after the disruptive event of COVID 19-pandemic (Erixon et al., 2022).

To achieve this objective the Chinese government has recently been implementing a series of targeted state policies and subsidies that allow domestic companies to progress quickly, to the detriment of foreign-owned companies, therefore domestic manufacturers get way more support from the government in China compared to other high-developed countries from the OECD[1] group as depicted in **Fig. 13** (Brown et al., 2023a)

Figure 13: China's MedTech support as share of revenue (%) compared to OECD countries

[1] Organization for Economic Cooperation and Development is an organization of 38 countries committed to democracy and market-autonomy (https://ec.europa.eu/eurostat/statistics, 2024)



Source: Brown et al. (2023a)

These industrial policies support the environment and work as an accelerator chamber for High-tech SMEs. The Beijing government has recognized these dynamic and fast developer entities as the chosen tool to complete the transformation of the Chinese medical sector. This framework has been called the "cultivation system" and is divided into four layers. At the bottom (provincial level) there are "Innovative SMEs", which focus on manufacturing. The outstanding reality is then selected and promoted to the next level (regional level) and is now identified as "Specialized SMEs", which grant access to various forms of national subsidies. "Little Giants" and "National Manufacturing Champions" occupy the top 2 pyramid positions. By the end of 2025 is forecasted that these two entities' classes will respectively account for 10.000 and 1000 units, those companies are the ones selected to expand the Chinese brand abroad (Brown et al., 2023b). The mechanism is efficient in tackling one of the main problems of the current Chinese industry, the rate of conversion of R&D achievement into actual new registered licenses, doubled (10%) since the implementation of the policies is still too low compared to the most developed countries (around 30%) (Zhang & Rao, 2021).

The next sections of this chapter will analyse these policies, capture the market actors' internal perceptions, and explain how they are willing to respond to this evolution.

3.4.1 Made in China 2025

Made in China 2025 (中国制造 2025) was launched in May 2015 by the State Council. It is the country's first ten-year action plan focusing on promoting manufacturing. It aims to transform China into the leading manufacturing country for high-end devices in nine key areas (Chinese Government, 2024). Among these strategic sectors, in 2020, President Xi Jinping vowed that the government would be doing more to support robotics, biomedicine and medical technology (Zhang & Rao, 2021). Traditionally Chinese companies adopted an OEM (Original Equipment Manufacturer) model, with the mere role of

manufacturer or retailer domestic agent for foreign goods. Nowadays national authorities are incentives domestic companies, to shift towards an ODM (Original Design Manufacturer) blueprint enabling them to become the developers, owners and producers of high-value-added goods with highly competitive advantages both in domestic and foreign markets (Chen, 2024). The results were evident, in 2020 the top domestic hospitals were using up to 50% of Chinese high-end medical devices and is estimated that this percentage will skyrocket to 90% by the end of 2030 (Erixon et al., 2021).

Hence, recently in 2022, the Sichuan, Zhejiang and Jiangxi regional governments have already stated that their medical institutions will be only supplied by domestic production. If we consider that the combined population of these three regions is 184 million people (equal to the population of Germany, Spain and Italy together) it is easy to imagine how this climb will be inevitable (Erixon et al., 2022).

3.4.2 Healthy China 2030

The secretary of the CCP in October 2016 ensured that health became an explicit national political priority through the approval of the Healthy China 2030 (健康中国2030) supported by China's Central Party Committee and the State Council (Chinese Government, 2024). Currently, China is on a mission whose objective is to enhance the overall health level of the population and the quality of its medical industry. Healthy China 2030 is the blueprint and is based on four fundamental principles, has five main objectives and utilizes thirteen indicators to mark the development and efficacy of the policy (Tan, Liu & Shao, 2017). These principles can be paired as follows: humanitarian and market-oriented. Starting from the humanitarian principles they are reflected in three objectives, namely Healthy level, Healthy life and Health services. Indeed, now the party has settled itself as an example to improve the quality of lifestyle and prevent rather than treat major health issues, this approach as cited before can be defined as people-centred (Tan, Liu & Shao, 2017). Life expectancy is one of the indicators, the mission before 2030 is to increase life expectancy to 79 years old and level all the other major health indicators in the highly developed country (Wang et al., 2019). Another one is the amount of healthcare paid by individual citizens; the aim is to reach 25% in 2030. This segment also comprehends environmental health, with the ambition to significative enhance the quality of air and water in Chinese territory (Yi, 2020)

Shifting toward market-oriented principles, Healthy China 2030 focus on reform, innovation and scientific development to enhance the medical complexity of the domestic medical device industry and, consequently, increase the revenue (Yi, 2020)

This policy connects the government's healthcare goals with its broader economic objective of transitioning from an import-driven model to one centred on domestic consumption (Chinese Government, 2024). This policy is crucial to support Centralized State Procurement of medical devices

and is an economic manoeuvre towards the realization of the government plan for national security (World Health Organization, 2024). The national security theme is the latest main effort of the Party, it is a complex concept and not easily explainable in its entirety within the scope of this paper.

However, for the document's purpose, it is necessary to understand that National security is the process of making the PRC independent in each sector of the economy or infrastructure considered of vital importance for the nation's security by the head of the Communist Party.

3.4.3 Medical technology in the 14th five-year plan (2021-2025)

In April 2021, the Chinese government published its 14th five-year plan (十四五规划) for 2021-2025 (Zhang & Rao, 2021). This program is particularly important because is the first after the COVID-19 pandemic when the event sheds light on the Chinese NHS's substantial weakness. The market experienced a shortage of high-end medical devices and the pressure on the healthcare system peaked. (Chinese Government, 2024).

Therefore, firstly the strategy sets the blueprint to achieve a high degree of independence in high-end medical supply. Consequently, investment in the high-tech goods categories aims to facilitate the growth of relatively new SMEs through financial support and strengthen China's presence in the global medical device industry by positioning at least 6 to 8 domestic companies among the world's 50 largest manufacturers, significantly improving the current situation where only four Chinese manufacturers rank within the top 100. (Brown et al., 2023b). Within the objectives, the party intends to expand healthcare accessibility in rural areas to reduce healthcare inequalities (Lin, 2022).

This strategy also calls for developing higher-value medical devices, encouraging Chinese manufacturers to enter fields such as radiotherapy and ultrasound, magnetic resonance, dialysis machines or pacemakers, and cardio-vascular stents. The central government expects Chinese local governments to set favourable fiscal, financial, and taxation policies to achieve these goals (Erixon et al., 2021). The institutions are also able to create demand for locally produced medical equipment and largely support R&D developments (Erixon et al., 2022).

To achieve all of that the policy draws from a rich toolbox, which also comprehends the localization of foreign enterprises, and enhances the flow of FDI in some specific market segments, e.g. AI-driven medical devices, ventilators, dental medical equipment (Brown et al., 2023a).

3.4.4 Centralised state procurement (CSP) and volume-base procurement (VBP)

The main industrial policy leading to these major changes is called centralised state procurement (集中采购) or CSP. The regulation has been made even more efficient towards the domestic medical device industry since it has been implemented together with the so-called volume-based procurement or VBP (带量采购). The policies combined produce a strong market-oriented environment that has nothing to do with pursuing global health or welfare goals, instead, it is all about driving massive and fast growth in the Chinese medical device market. Meanwhile, it aims to space room for Chinese manufacturers to recover the technology gap between high-end foreign medical devices and Chinese products, with the long-term ambition to develop a solid base and let the domestic brands expand abroad (Erixon et al., 2022). Although the policy was theorized one year before the outbreak of the pandemic in 2018 it was launched one year after in 2019, from this point onwards it saw several developments **(Table 7)**. The policy was tailored for pharmaceutical products, but soon it was extended to medical devices (Erixon et al., 2021).

Table 7: Centralised state procurement evolution timeline.

Launch Phase (2019)	Provincial procurement (July 2019)	First Cross-Provinces Alliance (May 2020)	2nd Phase Country full roll-out VBP (2020)	First Nationwide Centralised Procurement (July 2020)
Centralised state procurement explored as local trails at city-level, varied across regions.	Conducted at provincial-level to a higher standard; refined and standardized.	North-Alliance procurement led by Tianjin	Provincial centralised procurement implemented to majority of provinces with trend towards cross-province alliances.	State Council announced the first nationwide centralised state procurement of coronary stents.
			City-level centralised procurement to become of less importance.	More nationwide tenders for medical devices will come in 2021 and 2022.

Source: Erixon et al. (2021)

The policy works through regional, provincial, and city-level tenders. Both domestic and foreign manufacturers can participate in the tender. Consequently, the winner stipulates a contract for a selected product category and a specific territorial district. This contract allows the winning producer to operate in a bulk purchasing regime for a given product in each territory, therefore hospitals and clinics will be obliged to obtain supplies of that medical device from that winning company (Erixon et al., 2021). The other participants who lost the tender are cut off from the market with nothing left then attempt 1 or 2 years later when the tender for that given product will be open again (Erixon et al., 2022).

The goal is to optimize the cost of medical supplies through bulk purchasing, where hospitals or medical institutions are forced to buy a product in a higher volume at a minor cost, which draws an advantage

mainly to the manufacturer because it can now arrange production according to a contracted high-volume order scaling the economy and lower the production costs (Erixon et al., 2021).

Due to the policy objective, all the other commodities that come with medical device production such as education and training are more likely to be cut off by Chinese manufacturers since foreign producers are not legally allowed to do that, facilitating them to bid the lower price and win the tenders. Since 85% of medical care in China is provided by public hospitals and this public hospital, for specific goods categories can only be supplied by winning bidders manufacturers, this manoeuvre will undoubtedly enhance the Chinese domestic medical device sector (Erixon et al., 2022). Tenders are characterised by poor transparency and frequently favour Chinese companies because they display the condition to bid the best offers making them the winning bidder, in addition, this process sometimes borders on extortion (Erixon et al., 2021).

For someone new to China's environment this might be considered unacceptable. But this modus operandi is an inherently Chinese characteristic. Even if after the beginning of the Xi Jinping era the formal distance between the so-called “law in the books” and “law in action” is mostly reduced and the corruption rate sunk, in some sectors of the market the Chinese counterparts are undoubtedly favoured (Cardilli et al., 2021).

CSP is creating major impairment for foreign manufacturers. Their chance of winning the tenders is statistically lower than domestic players. In addition, the non-public procurement guidelines issued by the Ministry of Industry and Information Technology (工业和信息化部) extended the requirement of local content (25,50,75 or 100%) to a total of 315 items and among them, 37% are high-end medical devices (Brown et al., 2023a), therefore, to date foreign enterprises are obliged to choose to localize their business or leave the Chinese market.

3.4.5 CSP and VBP latest results

Since 2019, high-value consumables have undergone four cycles of national procurement, simultaneously joint purchases of medical consumables and provincial-level purchases have continued. The tenders involved 2243 domestic companies and more than 90% (2108) were awarded contracts.
The first two medical device classes that have seen the most winning tenders per unit are orthopaedic consumables followed by surgical needles, respectively accounting for 242,055 and 260,332 awards (Anhui sheng yiliao qixie hangyy xiehui, 2024).

From an economic perspective, the policy caused two specific phenomena: price reduction and price convergence. Percentage price cuts have been surprising, for instance, the 95% price reduction in coronary stents represents a remarkable achievement demonstrating the effectiveness of the Chinese

government's centralised state procurement policy. This reduction is particularly noteworthy given that coronary stents are high-end medical devices, traditionally characterized by high prices and substantial low-profit margins (Erixon et al., 2021). On the other hand, this significant price reduction is not completely unharmful. Hence, in the case of coronary stents the pressure to keep these low prices will be reflected in lower product capability, and the gradual decrease in product quality will affect patient treatment and people's lives. The pool of only 10 coronary stents selected for the centralized procurement resulted in 70% of Chinese doctors complaining and facing difficulties in applying the appropriate device to each patient (Erixon et al., 2022). Other important price reductions were orthopedics (55%), intraocular lenses (41%), pacemakers (50%) and nursing consumables (90%) (Erixon et al., 2021).

Market centralization enables a substantial rigidity in price variation and dynamic forces causing price convergence. It means that the gap between the maximum bid price and the average winning price is decreasing. Regarding the specific medical device sector, the phenomenon creates serious side effects. Indeed, the only requirement to win the tender is to lower the price as much as possible; to achieve this condition suppliers are incentivised to reduce the variety and quality of the products (Erixon et al., 2022).

From a stakeholder perspective, this policy, alongside important subsidies from the government allows Chinese manufacturers to become national champions and leverage the opportunity to impose themselves abroad in certain medical device categories' production, indeed Chinese MedTech SMEs received 1 to 3% more subsidies than bigger listed companies in other sectors (Brown et al., 2023b).

Among the companies that received the most funding between 2017-2021, we have Beijing Chulizhengda Medical Instrument with a total of €10.2 million, which has won tenders for hip implants (Shandong, Anhui, Zhejiang, Fujian) and knee implants (Anhui and Fujian), followed by Double Medical with €6.7 million total subsidies who won the Fujian (Knee implants) and Lifetech Scientific who earned €5.1 million from the government and won the Shandong pacemakers bids. In conclusion, is worth mentioning that Weigao Orthopedic has won knee implants and hip implant tenders in 7 different regions and Venus MedTech won the Jiangsu vascular international devices tenders with their high-end “VenusP valve” solution, totalizing a government subsidies value of €1.5 million (Erixon et al., 2021).

3.4.6 CSP and VBP consequences

However, significant economic results do not automatically translate into great success. To evaluate policy in a specific sector, such as medical devices, the variables to consider are much more than economic statistics. Therefore, CSP and VBP have both direct and indirect consequences on a delicate ecosystem.

Following the implementation of the policies, the Chinese medical device regulatory framework turns out to be one of the major obstacles for foreign manufacturers. China's regulatory framework wasn't explicitly designed to discriminate against foreign companies but in practice has the effect of impairing market access for the EU and other international firms, indeed the requirement regarding the approval of COO (Country Of Origin certification) is difficult to be satisfied since the imported goods must be first approved in its country of the manufacturer or where the market authorization is registered. In addition, if the medical device imported is a Class III high-risk product, strict clinical trials can be attended only afterwards the COO is obtained (Brown et al., 2023a).

However, each region's clinical trials differ, therefore, if a European manufacturer has already obtained the EU certification (CE) to sell its product in Europe, if the same manufacturer wants to sell the same product in China, it has to acquire the Chinese counterparty certification. For medical devices, the relevant certification required in China is known as the Medical Device Registration Certificate (MDRC). This certificate is issued by the National Medical Products Administration (NMPA) (Asia Actual, 2024).

This process translates into economic and time expenses for the foreign supplier while is an advantage to the Chinese domestic supplier, who can utilise these delays to catch up on technology, reduce operational costs and capture market shares. Since the innovation cycle for many medical devices is typically under two years and costly per device, companies may no longer manufacture or update that product by the time they receive Chinese approval (Erixon et al., 2021).

Another grey spot is investment regulations. Investment regulations are vague, including the definition of “Chinese” investment. Even if EU firms invest in China and try to become “local”, Chinese agencies do not appear to consider them “Chinese” enough to receive favourable treatment (Erixon et al., 2021).

Medical devices are not just simple goods, they need several after-sales services. Those services include regular product testing and education for medical staff. These activities are expensive, and they are the first features to be cut off by contracting on high volume. The main consequences are reduced service quality and impairment for Chinese customers to access the newest medical device technologies, this is also strictly related to the gradual diminishing of domestic and especially foreign suppliers (Erixon et al., 2022).

In conclusion, there is a significant international concern about centralised state procurement of medical technology. The foreign manufacturers think the policy will influence pricing and competition, gradually making it harder for foreign companies to access the domestic market. Using government procurement as an industrial policy tool is a well-known routine in the Chinese policy tool kit, as already cited is part of the Chinese characteristics, indeed the Chinese government has followed a similar path in other industries. The question that naturally arises is how the foreign market players, especially the

European counterpart, can answer this undisputable display of power and how the domestic players react to this development.

3.5 Foreign answer: Trade protection tools and protective measures against China

The main intent of the Chinese government's centralized state procurement policy was to create room for Chinese producers in the domestic market. But inevitably it resulted in impaired market access for foreign enterprises. The policy is intertwined with Chinese characteristics and comes with no surprise for Chinese area experts who recognize similar policy implementation in BRICS (Brazil) and low-income nations (Zambia, Tunisia, Philippines), historically influenced by the RPC (Jian et al., 2024). However, in Western perception, the advantage given to the domestic manufacturer, resulting in a significant loss of market share for foreign enterprises, can be considered a breach of the principle of fair international trade. This event generated a chain reaction recalling the attention of international institutions and economic powers such as European countries to formulate an answer to the Chinese manoeuvre. A process that most of the time leans toward a protectionist choice.

Based on breaches of international trade practices there are the terms for legal action. Supported by the European government, the manufacturer could file a WTO complaint regarding China's procurement policies, which eventually will result in duties or limitations on investment and export from China towards Europe. An analogue solution could be the International Procurement Instrument (IPI). The mechanism of the IPI allows the EU to restrict access to its public procurement market for companies, goods, or services from countries where European firms face restrictive or discriminatory measures (Erixon et al., 2021).

Theorized for the first time in 2012 after several rounds of revision in June 2021 is now in negotiations with the European Parliament. Indeed, this tool could be a suitable solution for China's medical technology sector but cannot be used yet (Healthcarelifesciences, 2024). This path could recalibrate the EU-China partnership, draw some red lines and in the long term create a more sustainable economic exchange environment (Zenglein & Holzmann, 2019)

On the contrary, forward-looking and diplomatic is the proposal of the World Bank Organization (WBG). The International institution recognizes that centralized procurement is an efficient solution for price reduction, inequity conditions and rapid market growth. However, the ultimate objective should be to create value by enhancing market players' numbers, competition and development, especially in the medical device sector where medical complexity, accessibility and output value are strictly related to global health. Hence, the WBG proposed a guideline for best practices of centralized state procurement implementation supported by the Asian Development Bank (Erixon et al., 2022).

Also, European institutions could navigate diplomatic routes, for instance, resume drafting the Comprehensive Agreement on Investment (CAI) which due to diplomatic inconvenience, the negotiation between the parties involved has been frozen. The CAI aims to create a more balanced investment environment between the EU and China and to guarantee an internationally acceptable standard level of transparency, licensing and authorization procedure. Such a condition allows us to negotiate better terms for market access and address issues related to state subsidies and support for Chinese firms. This protection extended to crucial sectors like medical technology can have significant results since European firms play a significant role in the supply chain (Cardilli et al., 2021).

As a major exporter to Europe's public procurement market, China is interested in maintaining this access and probably would not resist the agreement's development. In addition, Europe's effort should focus on drafting an agreement related to the healthcare sector and find some enforcement that obliges China to participate. European manufacturers can pressure further modification of the Trade-Related Investment Measures (TRIMS) in which China is already involved, however, a more tailored option related to the specific market is still the best solution (Erixon et al., 2021).

In conclusion, by fostering meaningful bilateral discussions, instead of utilising protectionism intervention, the foreign players can work towards eliminating discriminatory measures, such as local content requirements and domestic price preferences, which restrict market access. Historical precedents, such as successful dialogues in other sectors, such as wines and spirits, demonstrate the potential for achieving mutually beneficial agreements.

3.6 Chinese domestic answer: Going global the path of chuhai (出海)

In each chosen product category, centralized state procurement of medical devices has achieved important economic results, allowing the domestic Chinese market to grow rapidly and develop some of the biggest medical device manufacturers in the world. Overall, among domestic stakeholders, there was a positive feeling about this policy. However, after the latter development, they are starting to doubt the long-term effectiveness of this program.

Bulk purchasing led to a gradual decrease in medical device production costs and market prices, enabling more companies to gain market share and enhancing the inside competition. Besides the economic benefit, the medical device sector has now experienced a common trend in modern China: centralized state procurement intensified a phenomenon known as neijuan (内卷) (Ding, 2024). This word describes the involution of a market saturated by too many competitors.

In addition, the policy led to product homogeneity and decreased quality. After 4-5 years of market

growth, the Chinese domestic medical devices sector is expected to hit a plateau, which will slow down the development of new technology due to a lack of potential revenue in an immobile market. The consequences will be impactful, in this specific sector, research and development are crucial to becoming the market leader on a global scale (Ding, 2024).

Centralised state procurement not only affected net revenue and the overall quality of medical devices but also influenced the stock market. When a company loses its value in stock, it means that the value perceived by the investor is gradually decreasing. This damage cannot be ignored. Brand reputation and brand awareness are crucial factors in enhancing the perceived value of the product, especially if the Chinese manufacturer aims to expand abroad (Ding, 2024).

Asserting the state of the Chinese medical device market, expanding abroad represents the right pathway to avoid the current domestic saturation. Foreign market penetration enables Chinese manufacturers to leverage several strategic improvements in reducing production costs through economies of scale, building international brand recognition, and establishing a stronger presence in the global medical device landscape. This strategy and trend are known in China as chuhai (出海) or "going overseas" and has gained significant momentum since 2022 (Wu & Jiang, 2024). Recently, Chinese-manufactured medical devices, due to the key role played during the COVID-19 pandemic have significantly increased brand recognition overseas, a key aspect to consider when expanding abroad (Zhang, 2022).

Developing a global market presence presents significant challenges. These hurdles are mainly market entry barriers, regulatory compliance, cultural differences, and intense competition from established global players. Additionally, companies must consider the substantial financial investments required and the potential risks associated with operating in unfamiliar business environments (Wu & Jiang, 2024).

To tackle these challenges, Chinese enterprises are adopting a diversified portfolio of market entry strategies rather than relying on direct exports. Many companies are pursuing M&A to gain immediate market access and local expertise and mitigate the process of gaining geographical recognition. Others are establishing joint ventures with foreign partners or relocating or outsourcing production facilities outside China. These approaches and partnerships with local distributors and suppliers allow Chinese manufacturers to better navigate foreign markets while minimizing operational risks (Ding, 2024).

Regulatory frameworks heavily influence the choice of countries for expansion in the medical device sector, as this market is inextricably linked to product regulations that vary significantly across nations (Ding, 2024). While the United States and Europe maintain some of the most stringent regulatory requirements, Chinese medical device manufacturers have nonetheless managed to secure numerous certifications and approvals in these markets. This achievement not only demonstrates their growing

capability to meet high international standards but also the progress of the NMPA to align the domestic market to the international level, simplifying the future foreign market penetration for goods Made in China (Xu et al., 2022b).

On the other hand, the increasing protectionist measures in the EU and USA have prompted Chinese manufacturers to gradually shift their focus toward emerging markets in Southeast Asia, the Middle East, and India. This strategy is driven by China's growing influence within the BRICS alliance and by the opportunity to conduct trade in RMB rather than being solely dependent on US dollar transactions. This diversification in target markets and trading currencies provides Chinese companies with greater flexibility and reduced exposure to geopolitical tensions (Wu, Fang & Hossain, 2024).

In conclusion, while Chinese companies keep a significant presence in the low-technology medical product segment, which remains highly profitable, their strategic focus has shifted toward sophisticated medical equipment. This dual-track approach allows them to leverage their existing manufacturing capabilities while simultaneously establishing themselves as innovative players in the high-end medical device market, which remains the true objective of the Chinese government (Wu & Jiang, 2024).

Chapter 4: Comparative literature analysis

4.1 Structure and methodology of the comparative analysis

The medical device market is intertwined with other macro forces in modern society, in the analysis, these factors are identified and divided into 4 topics:

1. Post-pandemic global health situation
2. Medical device future developments
3. Ageing of the world population
4. Sustainability in the medical device industry

The scope is to evaluate how these aspects interact with the market and map the industry's border. Its comparative nature aims to identify contradictions or shared consciousness between international and Chinese domestic literature sources, it will help detect market strategies, and development directions and explore potential global objectives or signs of collaboration among market actors.

The organisational scheme adopted by the analysis is a text-by-text format. At the end of each sentence, the citation will be reported to identify the source of the information. As a final paragraph, I will provide a comprehensive evaluation, to gather the conclusions and assumptions discovered during the analysis.

International literature is defined by the use of the English language from non-Chinese authors and was retrieved from databases such as PubMed, Science Direct, and Research Gate. Chinese domestic literature was retrieved from CNKI, Wangfan (网范), and Px BaoGao (PX 报告). The selected literature will be gathered and presented on a table in the first section of each topic. Through the titled section, the table will present each chosen literature's distinctive traits, marked by a square in each cell.

The inevitable imbalance between the literature sources within the international and Chinese domestic academic environment and the need to cover 4 topics has led to thousands of results. Since the selection of literature follows a qualitative manual methodology respecting specific inclusion/exclusion parameters, this evaluation only aims to identify general patterns and support the comprehensive analysis of the medical device market. Therefore, the final chosen studies are equal to 20 domestic and 20 international papers and are selected as follows.

Firstly, 3 keywords per topic have been prompted for research. Then the timeframe has been restricted from 2018 to 2025, encompassing pre-pandemic, pandemic-era and post-pandemic literature. Consequently, the resources have been filtered to put in evidence only the studies with an acceptable academic weight, identified by the parameter of 50+ citations. In the end, throughout the title and abstract reading, the final most relevant sources have been selected.

Hence, the choice of source respects sharable and strict criteria which ensure the analysis is relevant, objective, and comprehensive. Recency and diversity of perspectives are necessary to guarantee the contemporaneity and the comparative feature of the analysis. Economic and data-driven criteria were also respected and some of the literature selected contains regulatory considerations. Ensuring that some of the literature covers relevant regulatory frameworks and how these affect market dynamics for medical devices is compulsory.

4.2 Topic 1: Post-pandemic global health situation

Table 8: Literature evaluating post-pandemic global health situation.

Authors	International	Domestic	Global Health	Economic focus	Long term focus	Regulatory Framework
Rossiter (2023)	■		■			
Taghizade et al. (2021)	■		■		■	
Chen et al. (2020)		■	■			
Yang (2024)		■	■		■	
Graham et al. (2022)	■		■			
Ma (2024)		■	■		■	■
Shi & Ma (2020)		■	■		■	■
Javed & Chattu (2020)	■		■		■	■
Kickbusch et al. (2022)	■		■		■	
Zhao (2020)		■	■		■	

4.2.1 Post-pandemic consequences

The current global health situation results from the recent overcame COVID-19 pandemic. The major proportion of this outbreak directly impacted the global health system policy and global health market trends.

The global health emergency exposed the weakness of the developed nation's health systems and exasperated those in less developed countries. It conveyed a clear warning, which has been converted into increased awareness by people and governments on global health (Yang, 2024).

The World Health Organization defines global health as the area of study, research, and practice that places priority on improving health conditions and achieving equitable access to treatment for all people worldwide (World Health Organization, 2024).

However, the term "global" has different interpretations based on the context in which it is used. It may refer to inherently global health issues, affecting multiple countries or populations, or to local projects that adopt a global approach and objectives. After the pandemic, it is safe to say that health issues are inherently universal and stress the necessity of cooperation between countries (Chen et al., 2020).

The pandemic influenced people's perception of physical and mental health, making them willing to invest emotionally and financially in self-care (Taghizade et al., 2021), with the side effects to wake people's attention towards the so-called Hidden Pandemic (Rossiter, 2023).

The Hidden Pandemic refers to the tangible and intangible health issues less evident than COVID-19 disease-like consequences (Rossiter, 2023).

For instance, mental illness and especially trauma are the main diseases related to the Hidden Pandemic (Rossiter, 2023). Traumatic injuries account for 11% of the current global burden of disease, resulting in nearly 5 million deaths annually and by 2022, traumatic injuries will be the third-leading cause of death worldwide. Therefore, injury is increasing, crossing international boundaries and affecting a large number of people, in the same manner that COVID-19 did in the recent past (Graham et al., 2022).

The global workforce has an average age of 35 years. This age group is statistically more susceptible to what's referred to as the Hidden Pandemic (Graham et al., 2022). Since the country's GDP growth is intertwined with the overall health outcomes, investing in addressing trauma and injury is likely to positively impact national GDPs. This trend significantly influences the medical device market, since the industry is closely tied to treating the conditions associated with these diseases. (Rossiter, 2023).

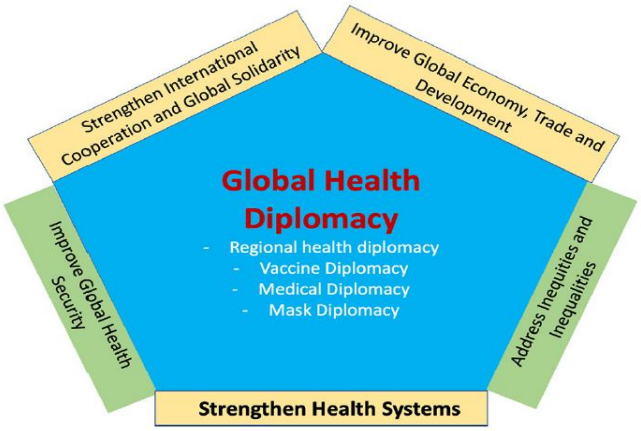
4.2.2 Global Health Diplomacy

The impact of the pandemic on the global economy has been so devastating that the widespread response of governments has been the adoption of protectionist manoeuvres resulting in the detriment of globalisation and the free market. Although international trade cooperation has suffered geopolitical rivalry and shifts, governments can strengthen the nexus between public health and trade policies

through Global Health Diplomacy, to fight global health emergencies and perhaps future pandemics (Shi & Ma, 2020). The categories of public health emergencies changed the concept of national sovereignty. The COVID-19 experience taught governments that health must be part of national security, but at the same time to fight a global health challenge is necessary to redefine the limits of sovereignty and enhance global collaboration (Zhao, 2020).

The pandemic sounds like a call on governments to move toward a diplomatic and multilateral approach that addresses public health concerns. In this context, the Global Health Diplomacy (GHD) will play a crucial role (Yang, 2024). According to the WHO, GHD connects public health, law, international affairs management, and economics, concentrating on negotiations and shaping the global policy climate for health (World Health Organization, 2024). The central tenet of GHD is for countries to work together in an international forum to address public health issues and its influence is spread into five key areas of implementation **(Fig. 14)** (Taghizade et al., 2021). GHD operates on three layers: bilateral diplomacy (direct connection between two countries), multilateral diplomacy (intervention of international institutions, e.g. WHO) and informal diplomacy (intervention of NGOs or private institutions) (Kickbusch et al., 2022).

Figure 14: Global Health Diplomacy key area of implementation.



Source: Taghizade et al. (2021)

GHD is widely focused on addressing health inequalities. The pandemic revealed the differences in treatment access between developed and developing countries. The Chinese academic literature is particularly sensitive to the topic since the disparities in treatment access are widely spread within its territory. Domestically, the Chinese government has already tackled the issue by implementing specific

policies, e.g. “Health poverty alleviation”, however, through the appropriate channel is one of those countries that demand intervention from international institutions such as WHO (Ma et al., 2024).

This international blueprint frees global health governance from political inflations by seeking to build strategic trust between governments by accumulating shared policies to achieve the same goals (Javed & Chattu, 2020)

Improving the global healthcare economy is one of the cited shared objectives and trade and development are strictly related to the medical device market. WHO through GHD employment aims to standardise the regulatory framework concerning the international trade of pharmaceutical products and medical devices (Taghizade et al., 2021), contributing to the cause largely presented in the previous sections. However, when it comes to trade, what scares governments the most is being able to protect their intellectual property rights.

Since 1994, IP protection has been ruled by the Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS) established by the WTO (World Trade Organization, 2024). However, The Doha Declaration on the TRIPS Agreement and Public Health adopted by the World Trade Organization during the ministerial Conference in Doha, Qatar, in 2001, was a milestone for the GDH and TRIPS evolution (World Health Organization, 2024). In Article 31 titled “Other Use Without Authorization of the Right Holder”, the declaration emphasizes the relationship between intellectual property rights and public health, particularly in access to essential medicines and medical devices in situations of national emergencies and circumstances of extreme urgency (World Health Organization, 2024). As a result, after the COVID-19 pandemic, the main international trend that can be clearly outlined is the need to normalize practices of international health cooperation and trade.

4.3 Topic 2: Innovation in medical devices and future trends

Table 9: Literature evaluating innovation in medical devices and future trends

Authors	International	Domestic	Global Health	Economic focus	Long term Focus	Regulatory Framework
Wreh (2023)	■		■		■	■
Lalwani & Suvarna (2021)	■		■		■	■
Dias et al. (2018)	■				■	■

Khalaj et al. (2021)	■		■		■	■
Davenport et al. (2019)	■				■	■
Zhang et al. (2024)		■	■		■	■
He & Wang (2024)		■	■		■	■
Zhang et al. (2023)		■			■	■
Kong et al. (2019)		■	■		■	■
Kong, He & Li (2018)		■		■	■	■

4.3.1 New medical device technologies

It has been cited multiple times that the medical devices industry depends on development due to their crucial role in life safety and human healthcare. This environment is heterogeneous, dynamic and constantly evolving supported by vast resources investment for innovation and industrialization.

Nowadays the development is led by two main drivers: the need for expansion in medical technologies and the increase in self-diagnoses demand (Wreh, 2023). It is a common mistake to think of medical devices as a tool whose implementation is solely to treat diseases. Experts in the field forecast that the main effort in research and development will be gathered in the prevention, diagnosis and health monitoring functions of medical devices (Kong et al., 2019).

From the imposed evolution of new-age tech medical devices, the industry development is achieving astonishing results in producing wearables (i), 3D printing diagnostic instruments and bio-printing implants (ii) and IoT-based devices guided by AI technology (Lalwani & Suvarna, 2021).

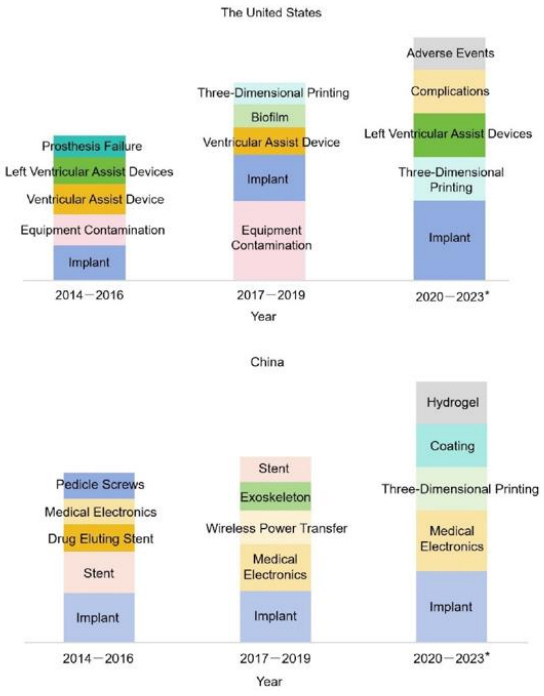
i. Wearable medical device technologies allow for contactless patient monitoring and treatment, both at home and in situations with limited direct patient access. The rise of sophisticated home medical devices like glucose monitors, insulin delivery systems, nebulizers, and oxygen concentrators has made it possible for patients to manage and monitor their health conditions independently. This trend is further supported by the remote-control capabilities of these smart wirelessly networked devices that enable healthcare professionals to supervise home-based

treatments, contributing to a growing preference for home care and self-treatment options over traditional in-person medical care (Dias et al., 2018).

ii. 3D printing diagnostic instruments and bio-printing implants are the next big thing in the industry. The main advantage brought up by this innovation is the hyper-customized levels of consummately suit a specific patient's anatomy, reducing significantly the percentage of rejection of the implant (Khalaj et al., 2021). Implantable medical devices and minimally invasive and non-invasive medical devices active and non-active such as dental implants, stents and artificial heart valves, left ventricular assist devices, and cardiac defibrillators are expected to benefit from this new technology (He & Wang, 2024).

From a global market perspective USA and China not only represent the first and the second largest medical device markets but also are the two leading countries in research and development outputs, however, their output distribution differs based on countries' priorities **(Fig. 15)** (He & Wang, 2024).

Figure 15: USA and China research focuses



Source: He & Wang (2024)

There are several challenges faced by the medical device market actors investing in the development of the industry. First of all, due to the sensitive scope of the given product, the biggest burden is to comply with the existing regulatory framework around the diverse national market, as mentioned in the

previous paragraphs, especially AI medical devices with their unique features and new management categories, are facing some difficulties in entering the market (Zhang et al., 2023).

For instance, the US where the regulatory institution is the Food and Drugs Administration (FDA) has recently added the Unique Device Identification (UDI) system which aims to enhance patient safety and enable the tracking of medical devices during recalls (refer to **section 1.2.1**), but it is costly and complex to adopt for the manufacturer. Similar solutions are expected to be implemented in other countries, especially in Europe increasing operational challenges for the stakeholders (Lalwani & Suvarna, 2021).

Moreover, the industry is facing financial hurdles, again in the US specific taxes have been added in the sector, lately suspended due to the COVID-19 emergency sanitary situation. On top of that medical device manufacturers should always pay attention to the protection of intellectual property. This action involves researching existing patents and assessing potential competition, as well as implementing strategies for patent defence to safeguard innovations. Protecting IP is vital as it fosters medical advancements, stimulates economic growth, and supports introducing new medical devices (Lalwani and Suvarna, 2021).

4.3.2 AI impact on the industry and China's contribution

Artificial Intelligence and IoT are driving revolutionary advances in healthcare technology. This segment is expected to transform the industry, and experts forecast it will produce a $147 billion market within the next 20 years (Kong, He & Li, 2018). AI-powered medical devices are transforming patient care through disease prediction, automated diagnosis, and personalized treatment planning (He & Wang, 2024). Smart wearables equipped with AI capabilities enable comprehensive healthcare solutions, from pre-surgical planning and medical imaging to gene sequencing and drug interaction analysis, while simultaneously reducing costs through remote monitoring systems. This integration of AI and IoT is reshaping traditional healthcare delivery into a more efficient, accessible, and precise system (Davenport et al., 2018). Massive implementation of this new generation of MDs allows national healthcare providers to build high-quality patient datasets, which act as a mine to extract data to improve every aspect of the industry for instance, clinical trials (Zhang et al., 2023).

These modern instruments in the industry are called artificial intelligent medical devices (AIMD) or software as medical devices (SaMD). At the moment the International Medical Regulatory Framework (IMDRF) classify SaMD evaluating two primary factors of intended use: the significance of the information provided for healthcare decisions and the context of the healthcare situation (categorized as critical, serious, or non-serious conditions) (Zhang et al., 2024). This classification framework also acknowledges the technological spectrum of algorithms, distinguishing between "locked" algorithms

that maintain consistent outputs for given inputs, and adaptive algorithms that continuously evolve their responses through automated learning processes based on new data analysis (Wreh, 2023).

Therefore, one of the greatest capabilities of this technology is to constantly optimise its performance by utilizing a machine learning model through RWD (Wreh, 2023). From this exceptional power arise two unique features referred to as “black box” and “evolution”. The black box refers to the opaque mechanism behind the AI decision-making pathways, which results in a lack of transparency, trust and accountability, making clinicians and regulators struggle to understand a particular diagnosis or decision.

The evolution refers to AI medical devices' ability to learn and update their algorithms based on new data. This dynamic nature poses regulatory challenges in maintaining consistent safety and effectiveness, as the device's behaviour may change after initial approval from the regulatory institutions (Zhang et al., 2024). In addition, other significative barriers are represented by the security of AI MDs and the protection policy behind personal data. In addition, from a logistical perspective, it will be hard to update the current health structure to efficiently operate this new technology and to train the healthcare personnel (Kong, He & Li, 2018).

Since 2018, the number of AI-related medical devices approved in China has significantly increased. Of most devices, around 79% were classified as Class II with moderate risk, whereas 21 % were classified as Class III with high risk. Most devices were categorized as medical device software, and the most common application was medical image processing. In terms of target body areas, devices related to cardiovascular treatment accounted for the highest proportion at 12.8%, followed by those related to the respiratory organs at around 11.3% and finally the brain at 6.7%. To sum up, the total number of AIMDs approved and produced in China is 256 devices. Of these, 202 are Class II medical devices, while 54 are Class III medical devices. These figures highlight rapid growth in the sector, especially after 2020, when the approval and production of AIMDs increased significantly, making China one of the leading countries in this key technology development (Zhang et al., 2024). Besides the large investment in R&D, the main Chinese competitive advantage is that China has the biggest patient database in the world. Nonetheless, since all the data comes from Chinese citizens the operation on the data is relatively free from controls or restrictions (Kong, He & Li, 2018).

All things considered, this evolution clearly outlined a diverse but shared healthcare pattern which will conduct the modern international medical device industry towards an individual-centred production which aims to monitor individual health status and manage chronic diseases gradually outside of hospital environments. This evolution will allow medical device manufacturers not only to open a new stream of revenue but also relocate the medical device company in the supply chain, putting them in a spot never covered before gradually near to the customers and patients. To get closer to the end user,

manufacturers now, more than ever, should leverage data and build intelligence into their products because it is fast becoming an essential part of the new device value proposition.

4.4 Topic 3: How the ageing of the world population influences the medical device market

Table 10: Literature evaluating how ageing of the world population influences the medical device market

Authors	International	Domestic	Global Health	Economic focus	Long term focus	Regulatory Framework
Stoodley & Conroy (2024)	■		■		■	
Kallestrup-Lamb et al. (2024)	■		■	■	■	
Chen et al. (2022a)		■	■		■	■
Chen et al. (2022b)		■		■	■	
Ma & Ma (2024)		■		■	■	
Qiu (2024)		■	■		■	
Chen & Dong (2024)		■	■		■	
Rudnicka et al. (2020)	■		■		■	
Tun et al. (2020)	■		■		■	■
Gölçek (2025)	■			■	■	

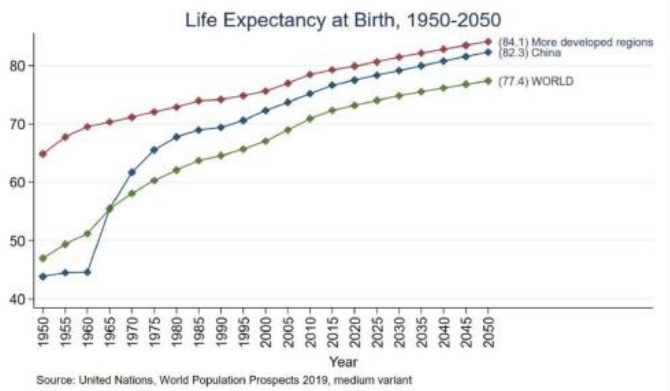
4.4.1 Global and China ageing population overview

The elderly population is growing faster, and in some countries, they have even passed the annual newborn. Therefore, this natural process nowadays gains a whole different meaning due to its impact on our modern society.

The WHO defines the ageing of the population as a geriatric phenomenon. This specific phenomenon is described as a multifaceted aspect of ageing that encompasses the unique health needs and challenges encountered by older adults (World Health Organization, 2024). Experts in the field forecast a life expectancy of over 60 years for 2.10 billion people by 2050 (Stoodley & Conroy, 2024).

Moreover, this general ageing is only partially influenced by the economic condition of a country, which means that even if, in the most developed areas of the world this phenomenon started more than 100 years ago, developing nations are also interested in this demographic transition **(Fig. 16)** (Stoodley & Conroy 2024).

Figure 16: Life expectancy at birth, 1950–2050



Source: Chen et al. (2022a)

Fig.16 displays this distinctive feature of the ageing phenomenon with an average health expectancy of 77.4 years for the rest of the world, which is not far from the most developed country. For the paper's purposes is worth noticing the China statistics and its current demographic situation (Chen et al., 2022a).

Over the last 40 years, China's economic development has allowed the population to access better healthcare services resulting in a general life condition improvement. These developments allow the country to become nowadays the home to 1/5 of the world's older population (Chen et al., 2022a).

China's ageing population also present presents unique features. While most high-income countries took approximately 50 years to double their elderly population share from 7% to 14%, China achieved this milestone in just 21 years, reaching 14.2% of its population aged 65 and older by 2021 (Chen et al., 2022a).

This rapid ageing trend positions China to become the oldest nation among the world's twenty most populous countries by 2065, with projections indicating that by 2050, its elderly population (65 and older) will reach 395 million people (Chen & Dong, 2024). This dramatic shift is driven by two key demographic

factors. Firstly, a steep decline in fertility rates, which plummeted from 6.1 in the 1950s to 1.3 in 2020 and secondly a significant increase in life expectancy, which rose from 44 years in the 1950s to 78.2 years in 2021. It means that those born between 1962 and 1975 defined as baby boomers have retired in 2022 due to the low age retirement in China (Chen et al., 2022a).

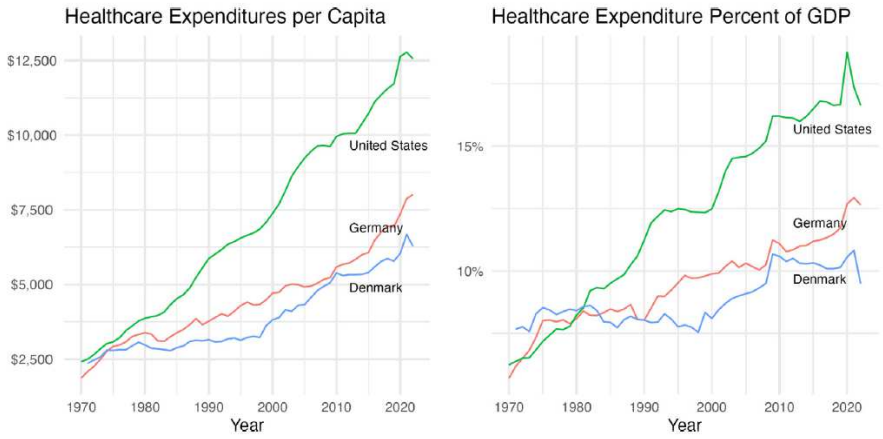
Recalling a global perspective the cause of the phenomenon is a reduction of child mortality, improved education, and better access to healthcare. Although all of that is a remarkable global success, this transition has environmental, social and economic impacts, which translates into serious challenges to face for the world's future population.

4.4.2 Ageing population impact on the economy, environment and society

- **Impact on the economy**

From an economic perspective, this phenomenon translates into an upward trend of per capita expenditures and per GDP expenditures **(Fig. 17)**, potentially becoming a threat to the sustainability of the entire healthcare system especially for developing countries (Kallestrup-Lamb et al., 2024).

Figure 17: Healthcare expenditures per capita (left) and per gross domestic product (right)



Source: Kallestrup-Lamb et al. (2024)

Taking as reference these three highly developed countries, from 2000 to today, per capita spending has almost tripled reaching its peak during the 2020 pandemic. Those healthcare expenditures are divided into ambulatory care, hospital care, long-term care and drugs, besides the latter, each expenditure has directly affected the medical devices industry resulting in increased demand and revenue for the sector (Kallestrup-Lamb et al., 2024). Therefore, the third demographic transition is

building pressure on the national healthcare system's financial sustainability. A country like China, particularly sensitive to the phenomenon should tackle this challenge shortly. Domestic literature proposed different solutions, one worth mentioning is the design of a highly sustainable “Elderly security system” built on three layers: economic security through investment in pension funds, service support enhancing long-term healthcare treatment and psychosocial well-being, which means creating a modern society suitable for the engagement of elderly individuals (Ma & Ma, 2024).

On the other hand, international experts have found that the ageing population could open new market opportunities reflecting the potential of the “silver economy”, i.e. the economic segment composed of older individuals who are willing to invest in healthcare or age-friendly housing and mobility solutions (Gölçek, 2025).

- **Impact on the environment**

The ageing of the population also impacts climate change; however, they interact in a complex manner. Recently we have been facing global warming and extreme weather emergencies, older and weaker people are the most sensitive populations to suffer these unusual conditions. However, the only functional instrument that a country has to face this global emergency are national and international government interventions, but older people are more likely to support short-term policies than long-term ones, resulting in a contradiction with the statement cited above. This may result in inadequate public support for measures to address climate change, resulting in poorer health outcomes for older people worldwide (Stoodley & Conroy, 2024).

- **Impact on society**

In some cultures, elderly people bring value to cultural heritage and are considered a precious part of society, however, in some developed countries the oldest part of their population often faces the case of loneliness, which influences the health of the elderly. Promoting a sense of community and intergenerational relationships should be nurtured to promote well-being in later life is crucial, especially with this ongoing demographic transition (Stoodley & Conroy, 2024). In Chinese culture, filial piety (孝) traditionally anchors the respect and care for elderly people, fostering cross-generational bonds that combat social isolation. However, urbanization and modern life have weakened this Chinese cultural heritage. To date, the ancient value of filial piety seems to be substituted by the so-called “Mimetic family” (似态家庭). These phenomena reshape the role of the community in the healthcare of the older portion

of the population, combining shared aid care models and emotional support. A vivid example of this cultural value in modern China is square dancing, a popular social activity where older adults gather in public spaces to dance together, promoting physical activity, social interaction, and community engagement (Qiu, 2024).

4.4.3 Red Herring Hypothesis

At first glance, these demographic changes could be considered a major threat to a country's economies, especially to the sustainability of the national healthcare system, in contrast, subsequent studies on the topic produced a theory which shifted the attention spot from the general ageing of the population to a specific period in the life of an individual, the theory is named “Red Herring Hypothesis” (Kallestrup-Lamb et al., 2024). The theory will be briefly introduced, however, the formula that demonstrates the hypothesis will not be cited, because it is not part of the objective of this thesis.

The "Red Herring Hypothesis" challenges traditional assumptions about healthcare costs and ageing by proposing that proximity to death, rather than age itself, is the main driver of healthcare expenditures. This insight suggests that healthcare spending is concentrated in the final years of life, regardless of when death occurs. Consequently, the financial burden of an ageing population on healthcare systems may be less dramatic than initially predicted, as the highest costs are linked to end-of-life care rather than the simple accumulation of years lived (Kallestrup-Lamb et al., 2024).

For instance, the demographic transition consequences on the Chinese economy are reflected in two aspects: First, more elderly people will have a long-term negative influence on the employable labour population, on the other hand, ageing population demands will be translated into more medical devices and social security expenditure, two essential driving forces for domestic economic growth (Chen et al., 2022b).

It is hard to give a unique answer to whether the ageing population will have a negative or positive outcome on the economy, however, empirical studies demonstrate a positive effect on the medical devices and healthcare industry where the elderly population can play an intermediary role through endowment insurance expenditure and medical and health care.

4.4.4 Healthy ageing and person-centred medical devices

Consistent with the thesis presented in the previous paragraph, healthy ageing can represent the solution to a sustainable worldwide demographic shift (Stoodley & Conroy, 2024). WHO has declared

the 2020-2030 decade as the decade of healthy ageing, demonstrating to the international community how important is this aspect to answer to the demographic transition (Rudnicka et al., 2020)

Healthy ageing is more than reaching the late stage of life disease-free, The World Health Organization defines it as the process of preserving the functional ability that allows an elderly individual to be independent and in good health (World Health Organization, 2024). This status can be achieved only through a coherent policy plan by the national government, combined with medical technology that enables long-term and preventive disease management (Chen & Dong, 2024). In addition, the Healthy ageing process is called to address significant inequality challenges, especially in related policy applications in developing countries (Rudnicka et al., 2020).

For example, the Chinese government through the long-term plan Healthy China 2030, established the importance of improving population health in advancing the country's long-term economic and social development goals. Part of this plan is fostering a so-called "90-7-3" model. The scope of the model is to ensure that 90% of old individuals can receive care directly at home, 7% in hospitals and 3% in nursing homes. The implementation of the framework results in a relief of pressure for family healthcare expenditure and consequently benefits medical devices and the national healthcare market (Chen et al., 2022a).

Similar models are being adopted worldwide, reflecting a transition from disease-centred care to personal-centred care, where prevention and monitoring are two key aspects. To date, IoT medical devices are already employed in elderly healthcare for detection, monitoring and intelligent assistance significantly contributing to the creation of smart clinical and living environments. In addition, the collection of biometric, behavioural and environmental data is also important for the improvement of the industry (Tun et al., 2020). This shift has a significant impact on the medical device industry, where instruments such as wearables or AIMDs will benefit the most in the future market (Chen et al., 2022b).

4.5 Topic 4: Environmental sustainability solutions in the medical device industry

Table 11: Literature evaluating environmental sustainability solutions in the medical device industry

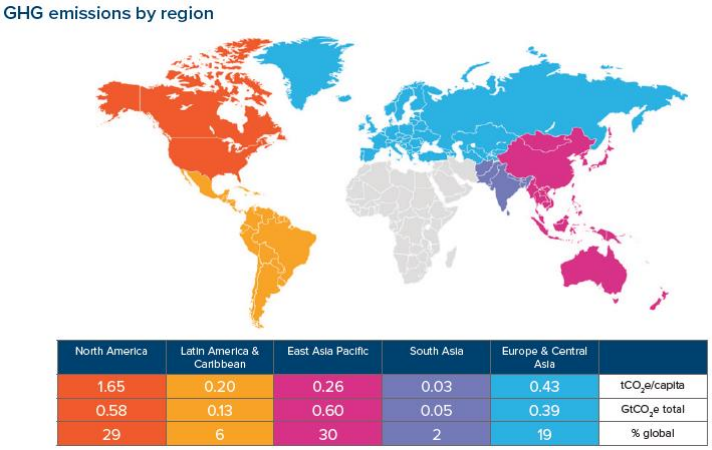
Authors	International	Domestic	Global Health	Economic focus	Long term focus	Regulatory Framework
Rizan & Bhutta (2024)	■			■	■	

Hovelling et al. (2024)	■			■	■	
Zhao et al. (2021)		■			■	■
Wu (2019)		■		■	■	
Zhu et al. (2023)		■			■	■
Li et al. (2023b)		■		■	■	
Wei et al. (2021)		■		■	■	■
MacNeill et al. (2020)	■				■	
Karliner & Slotterback (2019)	■				■	
Benedettini (2022)	■				■	■

4.5.1 Global carbon footprint of the healthcare sector

The healthcare sector's global carbon footprint accounts for 4.4% of global greenhouse gas emissions (GHC) (Karliner & Slotterback, 2019), which has a larger impact than aviation and shipping combined, with a prominent contribution in e-waste production (Hovelling, 2024). Climate change will represent the main future threat to global health leading to rising temperatures, increasing air pollution and rising sea levels. These natural phenomena have a direct impact on global health, for instance, extreme heat enhances the risk of cardiovascular-related illnesses and air pollution can cause respiratory disease and increase the spread of viruses such as HIV, AIDS and tuberculosis in the poorest areas. These factors combined will cause extreme pressure on the national healthcare systems, especially for less developed countries. This scenario is further aggravated by the forecast that climate change will lead more than 100 million people back to extreme poverty by 2030 (Karliner & Slotterback, 2019).

Figure 18: Greenhouse gas emission by region



Source: Karliner & Slotterback (2019)

Fig.18 shows how imbalanced healthcare global emissions are. If we sum up East Asia and North American emissions, which account respectively for 30% and 29% we almost reach 60% of the total footprint output, Europe and Central Asia generate another 19% and the remaining is divided among a vast number of countries between South Asia (2%), Latin America and the Caribbean regions (6%). The three biggest economies comprise 58% of global healthcare emissions, with the United States reaching 27%, China 17%, and the European Union as a whole accounting for 12% (Karliner & Slotterback, 2019).

Experts estimate that high-income countries' national healthcare could fluctuate between 3% to 10% of the total national greenhouse gas emissions annually (Wu, 2019), **Table 12** presents detailed information about China and Europe.

Table 12: Snapshots of China (on the left) and Europe (on the right) emissions

China health care	Value	Unit
Climate footprint	342	$MtCO_2e$
Emissions per capita	0.25	tCO_2e/ capita
Emissions as % of national footprint	3.0	%
Expenditure per capita	362	USD
Expenditure as percentage of GDP	4.8	%
% of footprint generated domestically	90.5	%
Health sector footprint equivalence to coal power plant emissions[32]	87.8	coal-fired power plants in one year

European Union health care	Value	Unit
Climate footprint	249	$MtCO_2e$
Emissions per capita	0.49	tCO_2e/ capita
Emissions as % of national footprint	4.7	%
Expenditure per capita	3668	USD
Expenditure as percentage of GDP	10.0	%
Health sector footprint equivalence to coal power plant emissions[32]	64	coal-fired power plants in one year

Source: Karliner & Slotterback (2019)

Based on the information displayed in **Table 12** the Chinese climate footprint is around 342 MtCO2e [2] slightly more than Europe, which is equal to 249 MtCO2e even if the emission per capita is lower and accounts for 0.25 tCO2e/capita[3] compared to the European statistics (0.49 tCO2e/capita) (Karliner & Slotterback, 2019).

Nearly all the environmentally harmful gas output comes from the industry supply chain. Hospital infrastructures are the main contributors to pollution. From their construction to the long-term sustainability of their operation, they require a large amount of raw material and high-voltage electric furniture to operate all the medical devices (Wu, 2019). Therefore, relevant Chinese domestic literature has suggested a construction model to complete the green transition of modern hospitals. To date, the clinical structure is governed by a canonical single-goal management model, which focuses on patient care. To enable the green transition, hospital management must shift into a multi-goal approach, combining different operational layers: healthcare quality, treatment efficiency and environmental sustainability (Zhu et al., 2023).

The medical device industry's supply chain is divided into direct and indirect processes. The direct section comprehends company facilities and company vehicles involved in actions, namely the market placement and final distribution of the goods. However, the greatest number of emissions are gathered in the indirect section which comprehends stages such as purchasing the raw material and electricity to sustain the production process, transportation and waste disposal (end-of-life treatment of the commodities). To the current state of the industry, the stages cited are mainly executed domestically resulting in significant national emissions. China in this aspect owns a negative record, accounting for 90% of its healthcare emissions coming from the national supply chain (Karliner & Slotterback, 2019). Therefore, it becomes self-explanatory the importance of finding sustainable solutions for the industry and the necessity to decouple the healthcare system from GHC emissions.

4.5.2 Medical waste disposal challenges

One of the main challenges to address in the green transition of the healthcare industry is sustainable waste disposal. Due to the product category medical devices and pharmaceutical goods may contain chemicals or biological hazards, that must be treated with attention and in compliance with

[2] MtCO2e stands for Mega-tonnes of Carbon Dioxide Equivalent. It is a unit of measurement used to quantify the amount of greenhouse gas emissions, expressed in terms of the global warming potential (GWP) of carbon dioxide (CO_2) (U.S. Environmental protection agency.gov, 2024)

[3] tCO2e/capita stands for tons of carbon dioxide equivalent per capita. (U.S. Environmental protection agency.gov, 2024)

environmental regulations, otherwise an inappropriate waste disposal could cause several second pollution consequences, for example, contamination of water sources and lands. The risk of poor hazardous waste disposal is higher in low-developed countries such as Iran, Thailand, Pakistan, Mongolia and African countries. China in particular has adopted a series of successful solutions to counter this challenge (Wei et al., 2021).

On top of that the most common medical devices are single-use products. Before the 80s' medical devices were intended to be reusable, prioritizing sterilization and disinfection processes. On the one hand, continuous innovation in material science paved the way for the implementation of low-cost plastic materials. The resulting cut infrastructure, production and inventory costs, contributed to making this product category the mainstream goods in the industry, with the side effects of relentlessly spreading the generalised perception that single-use devices were safer to infections rather than multiple usable ones (Benedettini, 2022).

During and after the COVID-19 pandemic, the most utilised single-use medical devices were surgical masks, and China was largely involved in their production. Even if surgical masks were worldwide recognised as one of the most useful prevention measures to the spread of the pandemic their production process involved the exploitation of some specific polymers named nylon 66. Nylon 66 is a silk-like thermoplastic, mostly made from petroleum with the addition of nitric acid during production. These raw material components are not recyclable, and waste disposal is not an easy task either. The COVID-19 pandemic in two years only, from 2020-2022, led to 900 billion global sales of surgical masks. Each of these resulted in 20.5 g of carbon emission, totalling more than 18 million tons of GHC output, the amount of emission resulted in 1.8 minutes of health life lost per person worldwide on average (Li et al., 2023b). Such extreme statistics highlight the importance of taking active solutions to firstly address the single-use medical device production and on the other hand, optimize the waste disposal of biohazard medical devices.

4.5.3 Sustainable solution for the medical device industry

- **Shift to a circular economy model**

To date, the vast majority of goods in the medical device industry are single-use instruments such as surgical masks, catheters, needles, gloves, syringes, wearables or prosthetic implants shaping the supply chain in a linear economy model, which results in a great amount of energy lost and medical waste. The realistic solution to the problem is a shift from the linear model to a circular supply chain model with the needed adjustment for the medical device's product category. A circular approach can minimize the

resource and energy output for the entirety length of the supply chain creating an energy loop which maximizes durability and the product's life. The stages that compose a circular economy model are reuse, reprocessing, repair, repurposing, and recycling (MacNeill et al., 2020).

In the medical device industry, the crucial phase is reprocessing. It is already mentioned that when it comes to the reutilization of a medical device the primary concern is the level of sterilization. During this process, the given good goes through a cleaning and decontamination operation because the end product needs to meet the required sterilization level to be eligible as re-utilizable (Benedettini, 2022).

The tendency to enhance the durability of medical devices is also supported by technological development. The scope of a linear economy is to cut the cost of goods production and maximize the revenue, however as we saw in **Topic 2**, the development is veering towards high-end medical devices, with a considerable cost of production. Shortly, being able to reutilize high-end products will result in a massive advantage. Moreover, the pressure to adopt a green model is not only provided by the main stakeholders of the industry but also by the people's consciousness of the sustainability of industries.

Looking at this topic from a supply chain point of view, in the current condition the reprocessing of medical devices would be mostly conducted by third parties. The healthcare infrastructure or the medical devices manufacturer, after collecting all the utilized medical devices would outsource this task to specialized companies in reprocessing capabilities. Such a scenario would open a new streamline of revenue and contribute to enhancing a highly remunerative sector such as the healthcare industry. The shift will release the pressure on the manufacturer of the cost and complexity of developing and managing this kind of infrastructure and more importantly obtain the necessary regulatory compliance from the related institutions (Benedettini, 2022).

To date, several regulation environments, including the United States, Japan, China, and the EU, allow Class I (infuser bags, ECG cable) and Class II (pulse oximeter sensors, ultrasound catheters) reprocessing. Things are slightly more complicated when it comes to reprocessing Class III devices (pacemakers, implantable) (Benedettini 2022).

On paper, the shift from a linear to a circular economic model seemed the logical solution to the medical device industry sustainability issue, however, there are still some ideological and practical barriers. The most widespread assumption is that single-use medical devices are less exposed to the risk of infection than reusable ones, but there is no scientific evidence to demonstrate this supposition. The risk of infection is multifactorial and setting up a study about this topic is unrealistic, due to the infinite number of variables. Practically speaking the diffusion of single-use medical devices is given by a high cost-effective ratio, which leads to anti-competitive behaviour between manufacturers and minimizes liability and complexity for hospitals and clinical infrastructures. On top of that, the needed adjustment

regarding the decontamination procedure of the national and international regulatory framework will require a massive effort by the responsible institutions (MacNeill et al., 2020).

- **Optimize the incineration process**

After the COVID-19 pandemic, bio-hazard medical waste has increased dramatically and needs to be disposed of as efficiently and sustainably as possible. Compared to single-use medical devices, the waste management of this environmentally harmful waste is more technical and sensitive. There are mainly three main methods of disposal: incineration, microwave sterilization and landfill, which are divided into different practices that are currently used in the industry, e.g. rotary kiln incineration, pyrolysis, incineration, plasma melting, steam sterilization and microwave sterilization (Zhao et al., 2021).

Due to their complexity, in this section, the process and the physical and chemical principle that governs each procedure will not be mentioned because it is outside the scope of this thesis, but the results of an interesting study carried out by Chinese researchers Zhao et al. (2021) regarding the most efficient method for producing energy from these chemical waste disposal processes are briefly presented.

Indeed, procedures such as incineration can produce a great amount of energy due to the extreme heat generated during the process. Based on this assumption scientists have conducted specific studies to identify the most effective way to dispose of this waste through incineration to obtain the highest heat-energy conversation ratio possible (Zhao et al., 2021).

The results show that microwave sterilization combined with landfill performed best environmentally while plasma melting had the worst environmental performance and the highest costs. Among all the technologies the main wasted resource was electricity, however, the consistent application of these processes will generate in the short term at least a 45% reduction in overall impact and will generate energy recovery efficiency up to a maximum of 83.4% (Zhao et al., 2021). This study highlighted how even the most dangerous disposal can be properly treated and converted into reusable energy, reducing the general impact of the medical device industry on the environment.

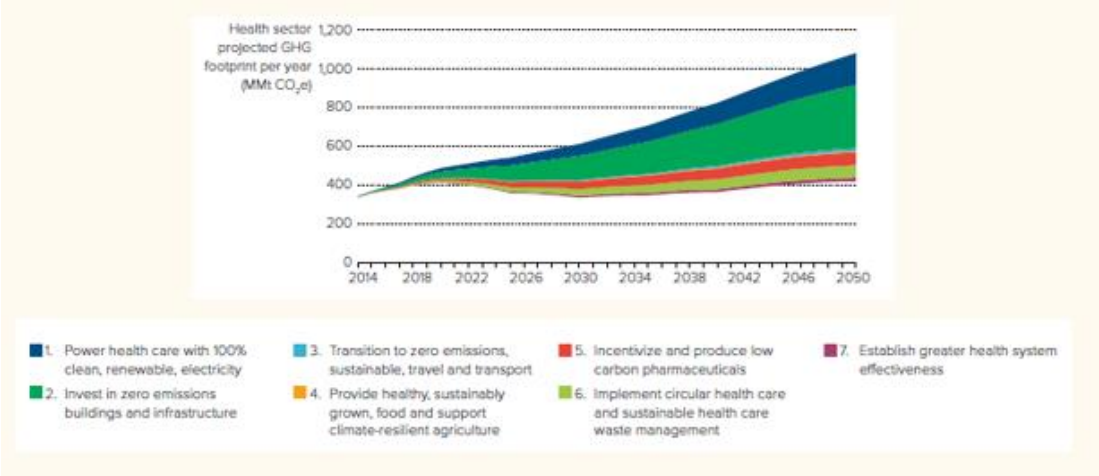
4.5.4 Policy recommendations for the sustainability of the national healthcare sector

The path to achieving a sustainable healthcare sector is clear but must be supported by national policy to ensure shared cooperation between the industry stakeholders. An insightful proposal could be to plan an efficient green transition starting from a systematic level supporting the categories with the vast majority of reusable medical devices through a central purchasing mechanism. This is a familiar framework to the industry's players since is the backbone of the Chinese national healthcare system. Besides that, conducting specific analysis and evaluation to identify on a national scale the high

environmental impact categories of products can help the authorities focus their effort to ensure the sustainability of specific categories (Rizan & Bhutta, 2024).

On the other hand, this ambitious objective cannot be achieved without promoting cross-sectoral climate and health action. There is a need for cooperation between supply chain actors, such as transportation, infrastructures, and energy providers, only all efforts combined can effectively reduce air pollution and protect public health from climate change. With the help of **Fig.19** is possible to figure out a quantitative measure of the actual potential reduction in emissions through the implementation of cooperative initiatives.

Figure 19: Emissions reduction potential for China's health sector from several combined policy solutions.



Source: Karliner & Slotterback (2019)

As **Fig. 19** shows in the long term is possible to achieve a total reduction in GHC emissions of almost 1100 MMt CO2e[4], thinking that China is the first country in the world to pollution from the national healthcare industry, this would represent an astonishing result, highlights how the green transition of the industry not only is necessary but also possible.

4.6 Comparative literature analysis result evaluation

The comparative literature analysis has revealed some interesting, shared visions and different

[4] Carbon dioxide equivalents are commonly expressed as 'million metric tonnes of carbon dioxide equivalents (U.S. Environmental protection agency.gov, 2024)

approaches to the topics presented in this section, and the results will be evaluated in this paragraph.

Overcoming the COVID-19 pandemic, there's a marked increase in health awareness among the public and governments, particularly regarding the Hidden Pandemic of mental health and trauma-related issues. This consciousness of the intertwined nature between population health and economic performance will generate increased investment in health sectors, including the medical device market.

From this chapter, Global Health Diplomacy has emerged as a valid path for facing global health challenges and enhancing international cooperation, also contributing to standardising the trend of regulatory frameworks to facilitate international trade while safeguarding public health interests. The tension between protecting intellectual property rights and ensuring access to essential medical resources during health emergencies remains a key focus area in both literatures. Overall, there's a paradigm shift towards viewing health issues as inherently global, necessitating collaborative approaches. The evident alignment between Chinese and international perspectives on these trends suggests a promising foundation for future collaborations in global health initiatives, regulatory harmonization efforts, and the advancement of the medical device industry on a global scale, potentially paving the way for increased international cooperation in addressing global health challenges in the post-pandemic era. In addition, some Chinese domestic literature reserves attention to the inequalities of health treatment access, both on domestic and international levels.

Looking ahead, both literatures suggest the same path of development for the industry with the research and development department working on the implementation of high-end technology in medical devices. However, a differentiation in the development path can be detected from Chinese domestic literature, it seems that more resources are being devolved into the research and production of high-end artificial intelligence medical devices enhancing intelligent self-care and AI governed ecosystem of healthcare structure such as hospitals or clinical institutions, give the Chinese competitive advantage related to this technological segment (e.g. vast number of data sources). Alternatively, international literature has emerged that medical devices industry stakeholders to quickly enhance their technology capabilities and effectively introduce smart offerings to their portfolio, may consider partnerships with other players, with a renewed streamline of collaboration. Is clear that Chinese and international experts consider the ability to leverage data-driven intelligence as a key imperative across the manufacturing and medical device landscapes. Furthermore, in both kinds of literature, I have found confirmation and support for the conclusion that the entire future industry is repositioning itself closer to the patient, a result which is also demonstrated by research on the following topic 3.

From Topic 3 analysis, given the fact that the ageing of the population is a worldwide and inevitable geriatric phenomenon, both international and Chinese domestic literature converged in supporting the

Red Herring Hypothesis and the necessity to plan and invest in a healthy ageing national policy. Except for the economic effect where the position does not differ, some differences can be detected in potential environment and social impact. Regarding sustainability, the Chinese population due to the number could effectively harm the environment if not properly managed, on the other hand, from a cultural perspective, Chinese society compared to European ones is more prepared to take care of the oldest generation. In conclusion from a medical device point of view, both literatures agree on the shift from a disease-centred medical device development to a person-centred medical device development and forecast a potential growth in the “silver economy” market segment.

The severity of harmful emissions from industry is a fact generally accepted. During the study, I never encountered a source who stated a different thesis from the shared conscience about the necessity to shift towards green sector development. The circular economy model is widely accepted in international and domestic literature; however, I have noticed how the keywords that distinguish academic literary production are slightly different. Indeed, international literature regardless of where it is produced, but mainly from the States or the European Union, is more focused on creating sensitivity around the topic and risks of climate change, also aggravated by the emissions of the medical device industry, paying more attention to theoretical formulations or a simple collection of empirical statistics to demonstrate the seriousness of the current situation. On the other hand, Chinese domestic literature is more centred on the demonstration of practice solutions, for instance, the most environmentally friendly method to dispose of biohazard or COVID-19 wastes or a sustainable multi-goal model for hospital management. The source of this difference could be intertwined in a different approach of Chinese expert which generally prefer to focus their effort on practice solutions rather than discuss theory. In conclusion, the analysis shows a general shared approach and ideas on every chosen topic, most likely due to the wide global scope of the latter. Nonetheless, some different academic approaches have been found through the analysis which sheds light on the inherent characteristics of researchers' principles between international and Chinese academics.

5. Conclusions

This comprehensive analysis presented the features shaping the international medical device market, reserving precise attention to the People's Republic of China and how it is involved in the industry. Therefore, before delving into the answers discovered by the study, it is good practice to restate the questions that moved the research.

Q1: What are the main characteristics of the medical device market in its current state?

Q2: What is China's role in the industry?

Q3: Is the international and Chinese domestic literature aligned or misaligned on various aspects of the topic?

The industry's uniqueness is evident in the factors identified as fundamental market drivers from the analysis. The main economic catalysts involved can be grouped into two large sets, the world's population medical conditions and the development of medical technologies. Regarding the first group, COVID-19 left behind remarkable attention on people's health. Besides canonical diseases, the medical device industry is called upon to develop solutions to answer a worldwide population suffering from lifestyle-related health problems. In addition, the third demographic transition commonly referred to as the ageing of the world population potentially represents one of the most important market drivers, especially in Asia, where most people live. On the other hand, medical complexity resulted as the main catalyst for revenue in the industry. R&D and manufacture of high-end medical devices represent the most economically valuable segment of the entire industry landscape. Combining the two assumptions can be affirmed with solid ground that the industry is relocating itself gradually near to the patient, implementing high-tech personalized solutions directly in the homes of the clients. This trend is consistent with the new technological solutions, namely IoT and AI medical equipment and big data applications in the healthcare industry. However, the analysis of market shares and growth rates revealed a stratification in market segmentation based on product types, where traditional medical devices (IVD, cardiology, imaging diagnostic) still stand in dominant positions.

The major barriers to economic growth are represented by the differences in regulatory framework among the regional markets. The process encompassing the procedures to obtain regulatory compliance has resulted in significant additional costs and wasted time identified as "medical device lag", nonetheless the study has presented insightful interventions from international institutions to enhance the harmonization and adoption of regulatory reliance to enhance medical device industry growth, development and sustainability especially towards developing national healthcare systems.

The study contributes to shedding light on the major differences between world regions in the medical device market. The data gathered and presented in the review of quantitative analysis chapter shows

that the industry's global share output is highly unbalanced and strongly points outward, it follows that the main economic characteristic is that the industry is export oriented. The network is dominated by export giants who influence their neighbourhood. The centrality of these countries such as the US, European nations and recently China has gradually increased through time to the detriment of intermediate countries, which historically act as a bridge to connect the various nodes of the international trade web.

It Is worth mentioning that in a highly globalised and unceasingly growing scenario, the true economic potential is not exploited due to a general protectionist attitude of the various world governments, the result of the recently widespread feeling of decoupling is attributable to the events that have shaken the world balance in recent years. This is also combined with a deliberate pursuit of personal national interests; China is no exception.

Moreover, managing the product life cycle of medical devices presents several challenges to the industry stakeholders. However, the study has presented a vast interest of international governments in promoting solutions to shift from a linear economic model towards a circular economic model.

After having explored the main aspects of the industry in detail, the role of the PRC and the path forward are clear. To summarise the findings organically, China’s role in the global medical device industry has been divided into three contributions. China is a major exporting country, it represents a model for developing countries that wish to emulate the same extraordinary growth path that China has had in the industry over the last 10 years, and it plays the leading role in the development and harmonisation of regulatory frameworks in APAC and streamlining the market access on a global scale.

Although China has been implementing national policies in recent years to enable its industries to become leaders in high-tech medical sectors domestically and abroad, it remains the largest exporter of low-end medical devices. Its global influence is mainly concentrated on developing countries in areas such as Africa and Southeast Asia. The repositioning of Chinese industry has been achieved through targeted policies such as centralized based procurement and volume-based procurement, which from an Atlanticist perspective can be defined as illegitimate, protectionist and accused of building a monopsony economic model. Therefore, implementing an objective judgement to a certain extent these policies do not create a favourable market for the already largely developed countries with a prominent role in the medical device industry, on the other hand developing countries in more areas of the world see Chinese policies as a successful model that can be emulated to embark on a similar path. Finally on the third, thanks to the NMPA's deep engagement in the international arena, through the implementation of regulatory reliance, China can play a crucial role in standardising the regulatory framework in APAC, opening up new revenue streams for the industry. In addition, through innovative

experiments in the Boao Lecheng Pilot Zone, China represents a pioneer in the implementation of RWD and RWE for medical device trials, reducing medical lag and simplifying market access. The remarkable Chinese evolution shows how China has moved in this sector from a copycat role to a pioneer and inventor with the clear objective of becoming the leading power in the industry. Several so-called “Sputnik moments” were identified during the study, among them there is the case of the “VenusPvalve” produced by Venus Medtech, the first surgical coronary stent designed and manufactured entirely in China to be marketed in Europe. A product that may symbolise the country's present and future.

Regarding the third question, due to the vastity of the topic analyzed drawing a clear-cut answer is impossible, however, a general alignment, with minor differences, can be detected between both literatures. For detailed acknowledgement of the comparative literature analysis, refer to **section 4.9**.

In the end, the limits of the study are the lack of data gathered from primary sources and economic model analysis personally conducted by the author, the shortage of detailed analysis of regulatory law directly extracted from official government institutions, and the manual qualitative approach on a vast number of sources in the comparative literature analysis which limited the robustness of the final evaluation of the given chapter. Therefore, further development can be conducted starting from these weaknesses to compensate for the critical points.

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