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Costa Rica's enablers and bottlenecks in moving along the medical devices global value chain

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Fotografía de portada: “Presentes”, conjunto escultórico en bronce, año 1983, del artista costarricense Fernando Calvo Sánchez. Colección del Banco Central de Costa Rica.

Facilitadores y cuellos de botella de Costa Rica para avanzar en la cadena global de valor de dispositivos médicos

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Resumen

El sector de dispositivos médicos es un motor fundamental para el desarrollo económico de Costa Rica, el cual representó el 37% del total de las exportaciones durante el 2022. Este documento analiza los principales facilitadores y obstáculos para la avanzar a lo largo de la cadena global de valor de dispositivos médicos hacia segmentos de mayor valor agregado. Utilizamos un método mixto que incluye análisis documental, 15 entrevistas con actores clave y estadísticas descriptivas de diferentes conjuntos de datos. Los resultados indican cinco facilitadores para la modernización: (i) una ubicación estratégica, estabilidad económica, política y social, educación, talento humano y un clima favorable para la inversión; (ii) un cambio en la estrategia de la agencia de atracción de inversiones hacia la cadena de suministro; (iii) el desarrollo de habilidades y talento especializados que la industria necesitaba; (iv) los programas de desarrollo productivo propiciaron el surgimiento de vínculos entre empresas multinacionales de dispositivos médicos y empresas nacionales; y (v) la existencia de habilidades especializadas. El sector también enfrenta tres obstáculos principales que dificultan su capacidad para aumentar el valor agregado doméstico: (i) las barreras culturales y la informalidad que restringen los vínculos hacia atrás; (ii) la persistente escasez de habilidades y la necesidad de más graduados bilingües en ciencia, tecnología, ingeniería y matemáticas; y (iii) la falta de incentivos que limitan la capacidad de profundizar la investigación y el desarrollo.

Palabras clave: Costa Rica, inversión extranjera, cadena global de valor, dispositivos médicos
Clasificación JEL: F14, F23, O21, O47

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The ideas expressed in this paper are those of the authors and not necessarily represent the view of the Central Bank of Costa Rica.

Abstract

The medical device sector is a critical driver of Costa Rica's economic development, accounting for 37 percent of total exports as of 2022. This paper analyzes the main enablers and bottlenecks in upgrading along the medical device global value chain into higher value-added segments. The mixed-method approach we use includes documentary analysis, 15 interviews with key stakeholders, and descriptive statistics of different datasets. Results indicate five enablers for upgrading: (i) a strategic location and economic, political, and social stability, education, human talent, and a favorable investment climate allowed companies to establish in Costa Rica; (ii) a shift in the strategy of the investment attraction agency toward supply chain helped identify key suppliers; (iii) the development of specialized skills and talent needed by the industry helped manufacturing more complex devices; (iv) productive development programs helped linkages emerge between multinational enterprises of medical devices and domestic firms; and (v) the existence of specialized skills enabled companies to consider Costa Rica for research and product development processes. The sector also faces three main bottlenecks that hinder its ability to continue upgrading: (i) cultural barriers and informality that restrict backward linkages; (ii) persistent skills shortages, and more bilingual graduates in science, technology, engineering and mathematics are needed; and (iii) lack of incentives that limit the ability to deepen research and development.

Key words: Costa Rica, foreign investment, global value chain, medical devices
JEL codes: F14, F23, O21, O47

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1. Introduction

Over the past two decades, the medical devices (MDs) sector in Costa Rica has undergone remarkable growth. In 2000, eight companies were in the industry, generating around 1,500 jobs and exports that represented 7% of the total. By 2022, the number of companies increased to 86, resulting in 12 out of the top 30 global MDs companies having production sites in Costa Rica, creating more than 50,500 jobs and exports that represented 37% of the total.[1] This has certainly increased exports of medical devices from Costa Rica (see Figure 1). It took the country 21 years to reach $3,528 million, but more than doubled it in just four years reaching $7,383.7 million.[2]

A previous study analyzed Costa Rica's position and potential for upgrading in the medical devices global value chain in 2013 (Bamber & Gereffi, 2013). The study found that Costa Rica exported complex medical devices, and that multinational corporations (MNCs) exported several sophisticated product lines, including bovine heart valves and intravenous pumps, and covered a number of market segments, including drug delivery systems, cardiovascular and orthopedic devices. Several firms, including Baxter, Boston Scientific and Hospira, also performed a growing number of engineering processes locally.

Yet, we do not know much about which are the main enablers and bottlenecks that the Costa Rican medical device industry faced and is facing in upgrading along the global value chain into higher value-added segments. Analyzing value added in the era of GVCs can provide additional insights that cannot be obtained by analyzing exports alone. In GVCs, multinational corporations (MNCs) might perform only a fraction of the total processes involving the final product in each country, shaping the production landscape with components traversing borders multiple times. The phenomenon of fragmented production globally characterizes GVCs, marking a significant evolution in the organization of economic activities. This interconnected and intricate web of value-added processes has become a dominant force, influencing the strategies of nations, companies, and workers. The value of the final output produced in the country and subsequently exported minus the cost of intermediate inputs and production costs, determines the DVA in gross exports.

Our paper is related to several previous contributions. First, Valverde-Carbonell (2023) identified key country-sector pairs with higher chances of increasing the DVA embodied in exports. Focusing on Latin American countries, he highlights sector D31T33 (Manufacturing n.e.c) of Costa Rica as pushing the sectoral specialization level. He finds that the specialization enhancement of this sector-country pair was driven by a shift in the product mix towards more complex products (medical devices), representing a sectoral upgrading process. While this study highlights the importance of using value-added to study GVC, there is a gap in identifying milestones behind the variations in the value added.

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[1] It is 13 of 30 considering that Johnson & Johnson would open a production site in Costa Rica. The top 30 MD firms ranking comes from MPO ("The 2023 MPO Top 30 Medical Device Companies Report" available at https://www.mpo-mag.com/heaps/view/11657/?nav=top_nav access on March 15, 2024) and the entry dates are from Cinde (available at https://www.cinde.org/es/sectores/manufactura-inteligente/ciencias-vida accessed on April 5, 2024).

[2] Throughout the document, all values are express in US dollars unless otherwise stated.

Second, Bamber and Gereffi (2013) were the first to use a GVC framework to analyze Costa Rica's position and potential for upgrading the GVC of MDs. While this study was fundamental, we take a different approach and instead focus on explaining what allowed (or limited) the country to upgrade along the GVC. By doing so, we hope that our exercise is useful for international policy makers that are concerned with upgrading within the global value chain of medical devices or related industries, and for local policy makers concerned with improving the business ecosystem of medical devices. More recently, Salazar-Xirinachs (2022) identified the main determinants of the recent growth in exports from the MDs sector in Costa Rica. Yet, this more recent study focuses on exports and not on value-added.

2. Methods

This study uses mixed methods where we combined documentary research with qualitative in-depth interviews and quantitative data to identify and analyze the main determinants of the Costa Rican MD sector in moving along the GVC.

We first carried documentary research for trend identification where we reviewed research papers (both peer-reviewed or not), books, and policy documents (mostly from multilateral organizations like the OECD and development banks like the World Bank and the InterAmerican Development Bank). The inclusion criteria comprised documents describing (i) theories of value-added generation within GVC in general or MD GVC specifically (also referred to as upgrading), (ii) national public policies or public-private partnerships for foreign direct investment attraction, retention, and heightening, and (iii) global and local trends in the MD sector. These documents allowed us to obtain a theoretical framework through which to understand and analyze upgrading in the local MD industry between 1995 and 2023. We describe the model in Section 3. The documents also allowed us to identify upgrading milestones in the Costa Rican medical device industry.

Subsequently, we identified key informants for qualitative in-depth interviews with the objective of understanding the main enablers and bottlenecks that allowed or limited these upgrading milestones from taking place. Interviewee selection was intentional, aiming for frontline policy makers or recipients in public, private, or civil society organizations. We conducted 15 interviews with 17 sector leaders from different organizations. These organizations included a foreign direct investment attraction agency (Cinde), two local medical devices cluster organizations (the Costa Rican MD cluster and CRBiomed), a risk and seed capital financial institution (*Sistema de Banca para el Desarrollo*), a public-private export promotion agency (Procomer), a certifying organism for products, processes, and services (Inteco), an accreditation body for university careers (Sinaes), a non-governmental organization devoted to research on economic growth (*Academia de Centroamérica*), the Ministry of Foreign Trade (Comex), a medical devices entrepreneur, and two academic institutions (IICIMED-UCIMED and *Tecnológico de Costa Rica*), (see Table A.1). These semi-structured interviews, lasting approximately one hour and a half, were conducted between November 2023 and February 2024. The interviews were guided by key questions adapted to the informants' expertise and the information previously collected in the documentary research. Appendix B include the questions guide for the interviews. Finally, the Analysis and

Consolidation of Results were carried out. In this phase, the research team synthesized the interview findings into this report.

Finally, we complemented the interview phase with quantitative data to test for the different hypotheses presented by the literature and the interviewees. We use trade data since 2012 from Comtrade to describe which medical devices products are being exported from Costa Rica to the different geographical markets. Our definition of the medical devices' product space is based on Table A1 of Bamber and Gereffi (2013) and includes all six-digit commodity codes under the four-digit codes 9018, 9021, and 9022, plus the commodity 900130 (contact lenses). We also gathered employment statistics from the most representative household survey in Costa Rica known as *Encuesta Continua de Empleo*. To test the reasons why medical device companies, decide to start operations in Costa Rica, we also built a database of newspaper articles with the company's reason for investing or reinvesting in the country. We searched each company's name in the websites of Cinde and La Nación using Google. Cinde is the primary source of press releases of Greenfield investments by OEMs in Costa Rica, but its website contains news articles only since 2016, and that is the reason why we complemented it with newspaper articles published by La Nación. In addition, an exhaustive search was conducted on each company's website to identify the reasons behind their decision to invest in Costa Rica. However, it was not possible to find news or relevant information directly from these corporate portals. We found 137 articles, of which of 70 cited the reasons why the company decided to invest in Costa Rica. We then grouped these reasons into different tags to understand which is the most often cited reason for investing or reinvesting in Costa Rica. We present the results in Section 5.1.

3. Upgrading along the medical devices global value chain

Ideally, in this section we would describe the evolution of upgrading along the GVC using different ways to measure the domestic value added in medical device exports from Costa Rica. Unfortunately, no such data at a sufficient level of disaggregation exists.[3] Without data on the value added of the medical device industry, we use an economic upgrading model for the medical devices GVC proposed by Bamber and Gereffi (2013). Gereffi (2010, p. 171) defined economic upgrading as "the process by which economic actors—nations, firms, and workers—move from low-value to relatively high-value activities in global production networks." Bamber and Gereffi (2013) model includes the following seven potential upgrading trajectories (see Table 1): *Entry into the value chain* when a new actor begins to participate in the value chain. *Product upgrading* describes the shift into the production of a higher-value product or service. *Process upgrading* describes improvements in efficiency in the production systems, such as the incorporation of more sophisticated technology. *Functional upgrading* describes the movement to new higher-value segments in the supply chain. *Chain upgrading* describes leveraging knowledge developed in one sector to enter another higher-value segment in the value chain. *Geographic end market upgrading* describes the incursion of firms into new higher-value end market segments. *Forward*

[3] A publicly accessible data on value added comes from the Trade in Value Added (TiVA) database of the OECD. TiVA is a collection of measures that provide insights into global production networks and supply chains beyond conventional trade statistics. TiVA tracks the origins of value added in exports, imports and final demand. However, a drawback is the need for trade-in value added at the product level, because TiVA data is classified at the sector level (that can be traced back to the ISIC classification).

and backward linkages describe the relationship between companies, industries, or sectors within an economy. Mechanically linkages increase the domestic value added of an industry by producing domestically a larger fraction of the value added that is being exported.

Using these upgrading trajectories, the following section shows quantitative evidence on the extent to which those trajectories took place in the medical device sector in Costa Rica.

4. Evolution of Costa Rica's participation in the medical devices' global value chain

4.1 Firms participating in the Costa Rican medical device industry

The first thing that should be mentioned about Costa Rica's participation in the medical devices' global value chain in the last 20 years is that its growth has been determined mostly by the participation of large multinational companies of foreign origin with export-oriented and efficiency-seeking strategies. Costa Rica's entry into the medical device global value chain began when Baxter Healthcare decided to open in Cartago in 1987 a plant to manufacture IV solutions and drug delivery systems. Since then, 86 foreign firms have entered the medical device industry in Costa Rica and this has increased its exports (see Figure 1).

Figure 2 shows the moment of entry of 41 selected medical device firms in Costa Rica, split into five periods of time generally used by the literature (Bamber & Gereffi, 2013; Salazar-Xirinachs, 2022). It also shows the country of origin and a star at the right of the company logo indicates if the company is one of the largest 30 companies of medical devices worldwide. As shown by the figure, 31 out of the 41 firms have headquarters in the US, but there are also OEMs from China, Denmark, Japan, the Netherlands, the UK, and Venezuela. Only one, Establishment Labs, is of Costa Rican origin, which began operations in 2009 and eventually became the first Costa Rican company to quote on Nasdaq.[4] By 2023, 14 of the top 30 global medical device companies have production sites in Costa Rica. Milestones include the entry of Boston Scientific in 2004 with a plant to manufacture devices for minimally invasive surgeries. Abbott's medical devices branch entered in 2010 with a plant to manufacture different types of cardiovascular catheters. Edwards Lifesciences entered in 2015 with a plant to manufacture heart valves, and Boston Scientific R&D entered in 2014. Since 2020, ten OEMs and seven suppliers entered, including Terumo blood and cell technologies. In addition to the initial investment, our database of newspaper articles and key informant interviews (KII) demonstrate that firms usually also reinvest in the country by expanding their operations.[5]

Since manufacturers tend to specialize in one or more specific end markets, the entry of a new OEM suppliers helped the local MDs sector to diversify extensively into different market segments, but has taken place also intensively, with the number of firms in each market segment increasing

[4] Establishment Labs is now a global medical technology company focused on improving patient safety and aesthetic outcomes, initially in the breast aesthetics and reconstruction market, designing, developing, manufacturing, and marketing an innovative portfolio of silicone gel-filled breast implants.
[5] As further explained in Section 5.1, the Free Trade Zone regimen of Costa Rica provides companies with the option to reinvest to keep the benefits. This could create an incentive to keep reinvesting in the country.

over time (see Figure A.1). This diversification accelerated considerably between 2001 and 2012 but is slowing down more recently.

Since most of the firms are US origin, it is understandable that, in the case of Costa Rica, the US is the main destination for MD exports from Costa Rica. Yet the exports to Japan and the European Economic Area and Switzerland have multiplied by a factor of 65.6 and 5.6 since 2012, respectively (see Figure A.2). This is important from a value-added point of view, because these are markets with stringent health regulations, increasing the value added of the devices manufactured locally. Exports to Latin American countries have doubled between 2012 and 2022 but still represented just 2% in 2022.

By classification, from lower to higher unitary value (see Table A.2 and Figure A.3), disposables were the most exported product category in 2001 but have been displaced gradually in the last 20 years by medical and surgical instruments and by therapeutics. Exports of capital equipment products have been increasing in the last decade.

4.2 Main medical devices exported from Costa Rica

Medical device complexity varies considerably even within the same category, highlighting the importance to analyze further the medical devices exported from Costa Rica. Panel A of Figure 3 shows the four most exported MDs from Costa Rica, in millions of USD, and Panel B shows the Costa Rican exports as a share of global trade (also see Table A.3). Below, we also make a deep dive into two products that represent the largest share in global trade.[6]

Catheters. According to Panel A, the most exported devices have been catheters. Catheters are sterile thin tubes, of different lengths and sizes, made with medical grade materials, often silicone but also polymers (polyurethane, PET, polyimides), and sometimes coated with a hydrophilic surface (a slippery film). By 2022, Costa Rican exports of catheters represented 5.3% of the global trade of catheters, positioning the country as the seventh largest exporter of catheters worldwide. Catheters are also the main product of export from Costa Rica overall (among all products, even agriculture). Figure A.4 shows that 63.4% of catheters exports in 2022 from Costa Rica goes to the US (followed by European countries). Since the US is the largest buyer, Figure A.5 also shows the main source countries of US imports, led by Mexico (which represented 36.9% of all catheters imports to the US), and followed by Costa Rica (13.6%). Dominican Republic is the seventh largest source country (3.1%). The most common type of catheters exported from Costa Rica are “IV drug delivery systems” and “other types of catheters” (see Figure A.6). According to shipment data from TradeDataPlus.com, Baxter and Abbott Costa Rica are the largest exporters of catheters, accounting for 78.2% of catheters’ exports. Baxter’s production specializes in seven medical devices related to irrigation and transport of fluids from an external source to the human

[6] The growth of three products (catheters, cannulas, and similar products; other medical, surgical, or dental instruments; and artificial parts of the body excluding artificial joints) explains almost 100% of the growth in exports between 2020 and 2021. The growth rate of MD exports is given by the growth rate of each product multiplied by their corresponding shares in total MD exports, $g_y = \sum_{i=1}^{n} g_i s_i$. Then, the share of the growth in MD exports that is explained by a specific product i is given by g_i/g_y.

body (Bastos-Vega et al., 2022). Abbott on the other hand is the largest exporter of coronary dilatation catheters.

Heart valves and heart occluders. The third most exported MD from Costa Rica is “artificial parts of the body excluding artificial joints” (HS code 9021.39). In the case of Costa Rica, HS code 9021.39 includes mostly biological heart valves and heart occluders. Costa Rica is the third largest exporter in this category, with its exports representing 8.3% of the global trade in 2022. Figure A.7 shows that 60.4% of exports in this category from Costa Rica goes to the US (followed by European countries). Again, since the US is the largest buyer, Figure A.8 also shows the main source countries of US imports, led by Ireland (which represented 62.7% of imports to the US), followed by Costa Rica (13.3%). Mexico is fourth with 4.1% and Brazil is 12th with less than 0.1%.

Heart occluders is a type of device that is placed in the heart to treat a heart defect known as a patent foramen ovale (PFO).[7] The occluder is a Class III device that requires biocompatible materials because it remains permanently implanted in the heart. Prosthetic heart valves are artificial valves used to replace damaged or diseased heart valves. Shipment data from TradeDataPlus.com indicates that Edwards Lifesciences, Abbott, and Boston Scientific are the largest exporters in this category (accounting for around 64.8% of the exports). Two different types of surgical prosthetic heart valves exist (see Figure A.9), mechanical and biological, of which Edwards Lifesciences is a leading manufacturer. In Costa Rica, Edwards Lifesciences began with a dry plant assembling heart valve parts, receiving all raw materials from its headquarters in Irvine, CA. Two years later, through an expansion to a wet plant, it moved to manufacturing a transcatheter heart valve and then to surgical valves. Surgical BHVs are either of porcine origin or are synthesized from a sheet of bovine pericardium that is mounted on a frame or stent and covered by fabric, which serves as a sewing ring. BHVs assembly requires significant expertise and manual assembly labor. In Costa Rica, Edwards imports around 95% of its raw materials from the US, include the animal tissues for BHVs where no local provider exists (possibly due to scale, traceability, and cattle farming practices needed by the OEMs).

4.3 Costa Rica competitiveness by medical device

Figure A.10 shows the remaining HS codes of medical devices. This figure highlights that while the country seems to be competitive on average in the medical devices industry, considerable variation remains in Costa Rica’s competitiveness across the different devices. Some devices left the market, like syringes, whose exports decreased to a nonsignificant value between 2012 and 2022.[8] But other devices enter the market as their export value increased from a nonsignificant to a significant value due to the entry of a new OEM which affects the type of new devices that

[7] According to the Mayo Clinic, a patent foramen ovale (PFO) is a hole in the heart that didn't close the way it should after birth. The hole is a small flaplike opening between the upper heart chambers.

[8] Syringe exports from Costa Rica decreased continuously since 2017 to a value of $132.1 thousand by 2022. We tried to understand why Costa Rica syringe exports decreased to a nonsignificant value. We asked the KII about this phenomenon and searched news articles, but unfortunately, we could not find an answer. A hypothesis is that OEMs moved the production of this high-volume, low-value-added device to a lower-cost facility.

begin to be exported.[9] The figure also highlight future opportunities for export expansion as the country has not yet exported several devices whose manufacturers can be attracted through FDI (e.g., dental drill engines).

So far, we have described Costa Rica's participation in the medical device global value chain. In the next two sections, we describe what are the main enablers and bottlenecks that Costa Rica is facing to continue advancing in the global value chain of medical devices. These enablers and bottlenecks explain some of the upgrading milestones that the Costa Rican medical device industry experienced and were constructed from the analysis of the qualitative in-depth interviews with key stakeholders.

5. Why did upgrading took place in the medical device industry in Costa Rica? Main determinants contributing to the growth in domestic value-added

5.1 Innate and acquired factors explain why medical devices companies and their suppliers chose to operate in Costa Rica

Costa Rica entered the medical device global value chain in 1987 when Baxter began operations and was eventually reinforced with the entry of 86 OEMs and suppliers. The success in attracting foreign investment in medical devices is also reflected in other knowledge-intensive sectors like advanced manufacturing and corporate services (including shared services, contact centers, and back office). The significance of these results made UNCTAD (2002) highlight Costa Rica as one of the six most successful countries that had made large strides in improving their export competitiveness based on the growth of FDI inflows and upgrading in the composition of its exports. As a matter of fact, FDI inflows to Costa Rica increased from $162 million in 1990 to $3,045 million in 2022, ranking first in the Greenfield FDI Performance Index for two consecutive years (2022 and 2023) as the country that attracts the most FDI relative to its gross domestic product (GDP).[10] So, the question of why MD OEMs and suppliers decided to invest in Costa Rica is broader and includes which features have made the country more attractive to FDI.

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[9] Theragenics is a manufacturer of needles and sutures for special surgeries (see https://www.comex.go.cr/sala-de-prensa/comunicados/2014/agosto/theragenics-instalar%C3%A1-planta-de-manufactura-m%C3%A9dica-en-costa-rica/ visited on March 15, 2024). Exports of orthopedic appliances have also expanded considerably following a large investment from Medtronic that began in 2020 to increase production capacity. Contact lenses (not included in the original Bamber and Gereffi classification of MDs) entered the market in 2012 following the entry of CooperVision. Artificial teeth entered the market in 2014 following the entry of Viax Dental Lab. Regarding capital equipment (panel E), four products entered the market. Electro-cardiographs in 2019, ultrasonic scanning apparatus and computed tomography in 2021 following the entry of Terumo, and x-rays parts and accessories in 2022.

[10] This increase in FDI could be related to nearshoring (a business strategy of relocating some or all of the company's operations to a country closer to its headquarters), a phenomenon that accelerated since trade relations between the U.S. and China deteriorated in 2018 and soon after the arrival of COVID-19 in 2020. Unfortunately, there is no evidence that this is happening locally, and as shown throughout this section, it also responds to innate and acquired factors of Costa Rica. FDI data according to UNCTAD (see https://unctadstat.unctad.org/datacentre/dataviewer/US.FdiFlowsStock accessed August 7, 2024), and Greenfield FDI Performance Index according to FDI Intelligence (see https://www.fdiintelligence.com/content/data-trends/costa-rica-again-tops-list-of-fdi-overachievers-82539 accessed August 7, 2024).

Case studies from Costa Rica provide hypotheses explaining the country's results attracting FDI in the sectors of high-tech (Spar, 1998; Larraín et al., 2000; Rodríguez-Clare, 2001; UNCTAD, 2002; Cordero & Paus, 2009; Comex, 2012; Román et al., 2014; Oviedo et al., 2015) and medical devices (Alfaro, 2024; Bamber & Gereffi, 2013).[11] We describe these key policies below, while taking into consideration that "Costa Rica's recent string of achievements in the technological area are the result of a series of mutually reinforcing policies and events (some of them dating back to the nineteenth century) that have converged in the past years" (Rodríguez-Clare, 2001, p. 312).

Costa Rica's political and social stability and a strong emphasis on education as the basis for democracy and development. Costa Rica is the oldest democracy in Latin America. Spar (1998) is the best source of information describing Intel's site-selection process in Costa Rica, a decision that marked a pivotal shift in FDI attraction policy. The study mentions (p. 13) that Costa Rica, "Occasionally described as the "Switzerland of the Americas (…) has a long history of political and social stability, rare commodities in most of Central and South America. The country has been a full-fledge democracy since 1948 and has had none of the uprisings or civil unrest that plague many of its neighbors… Civility, property rights and the rule of law are solidly established in the country, which has only seen two periods of armed conflict (1917-1919 and 1948-1949) since declaring itself as a sovereign republic in 1838. Unique to the world, Costa Rica has not had a military since its turn to democracy in 1948." This democracy has been built on education.

Costa Rica's emphasis on education began early in the 19th century, when the country had a literacy rate that was among the highest in the Americas. This commitment to education was later reinforced with the accession to make primary education constitutionally mandatory, the creation of the first public university of the 20th century in 1940, and the creation of three more in the 1970s. The public universities generated the supply of scientists and engineers needed for the industrial sectors that grew in the 1960s and 1970s, and for the state-owned companies in telecommunications, electricity, agriculture, industry, water supply, and infrastructure. Thanks to these past investment policies in education, Costa Rica's adult literacy rate is close to 100 percent, and primary school enrollment is nearly universal. However, the country still shows high dropout rates of students at the secondary and tertiary levels of the system. A considerable number of people have some knowledge of English, a result of the introduction of foreign language instruction in primary schools in 1994 and the prevalence of English-speaking tourists. These educational results are considerably better than most of its peer countries at the same distance or less to the US as reflected in the EF English Proficiency Index (EPI).[12]

The legacy of a protectionist development strategy known as import substitution that bequeathed institutions and incentives to promote the growth of non-traditional exports through subsidies and partial tax exemptions. The import substitution strategy aimed to

[11] Another interesting research area with considerable studies is related to the determinants of foreign direct investment, but we will not describe it here.
[12] Available at https://www.ef.com/wwen/epi/ accessed on August 22, 2024. See also https://www.elfinancierocr.com/economia-y-politica/costa-rica-tiene-el-segundo-mejor-ingles-en/424U4DD7CFDF7PBWRLTZGQSUD4/story/ accessed on August 22, 2024.

protect the domestic manufacturing sector from competition outside the Central American Common Market. Despite its increased tariff and non-tariff barriers to international trade, the strategy was accompanied by institutional building that promoted growth of non-traditional exports through subsidies and partial tax exemptions.[13] In particular, the Export Processing Zone regime emerged in 1981, allowing companies to import all their inputs and equipment tax free and avoid paying income tax for eight years, paying only 50% of taxes due for the next four years. This system was designed to attract FDI and would eventually become one key element in the attraction of high-tech multinationals.

A shift in the development model towards a process of trade liberalization, that was accompanied by institutional building and adjustments to existing institutions and incentives. The "demonstrations of openness and liberalization" (Spar, 1998, p. 3) began in 1982, when Costa Rica experienced the worst economic crisis so far. With no majority opposition and driven by international organizations, the crisis led to a widespread consensus that the development model needed to shift towards a process of trade liberalization. Some adjustments to existing institutions and incentives included the creation in 1983 of the first public entity responsible for formulating and implementing foreign trade policy, the Ministry of Exports (Minex). The Export Contract, active between 1984 and 1999, provided fiscal incentives where exporters enjoyed an income tax holiday, tax-free imports of equipment and inputs, and received a generous subsidy equivalent to 10% of the value of their exports. This system was designed to help domestic companies change their strategy from one designed to the domestic and Central American Common Market towards one where they had to compete in open and competitive world markets. Costa Rica further liberalized its trade policies and entered into both bilateral and multilateral free trade agreements. By 1990, Costa Rica formalized its accession to the General Agreement on Tariffs and Trade (GATT)—which later became the World Trade Organization (WTO)—and by 1995 signed its first free trade agreement, with Mexico, later resulting in 15 trade agreements signed to date. By 1990, the Export Processing Zones were reformed into the Free Trade Zones (FTZs). FTZs wave custom duties and provide tax incentives to companies establishing export-driven manufacturing operations (see Table A.4), and "have resulted in one of the better export processing zone systems in the developing world" (FIAS, 1996, p. vi). To support this process, the government also invested in upgrades to the national airport, ports, and customs systems to enhance international trade infrastructure.

Geopolitical interests, influenced by the Cold War rivalry between the U.S. and the Soviet Union, also played an important role in creating initiatives which helped Costa Rica to stand out in a turbulent region and to attract FDI.[14] The first initiative was the Caribbean Basin

[13] Since 1968, there was a center (Cenpro) aimed at promoting exports and streamlining international trade procedures. Since 1976, there was also an Export Promotion Law intended to complement Cenpro's efforts by promoting non-traditional exports to markets outside Central America through subsidies on export value, partial exemptions from import duties, and partial exemptions from some domestic taxes on imported raw materials used in the production of goods destined for export.

[14] Central America in the 1980s was characterized by internal political conflicts and influenced particularly by the Cold War rivalry between the U.S. and the Soviet Union. USAID had a geopolitical interest in promoting changes in economic models as part of its strategy of external economic aid for the development of countries as an element of the fight

Initiative (CBI), of which Costa Rica was a member from the beginning, enjoying duty-free access to the US market (zero import duties for nearly all manufactured and agricultural products). The CBI was part of a comprehensive foreign policy program of the Reagan administration "to promote economic revitalization and facilitate the expansion of economic opportunities for the Caribbean Basin region." Certain trade preferences and other benefits were granted to countries in the region beginning in 1984. These tariff and trade measures were intended to promote economic revitalization and expand private sector opportunities in the Caribbean Basin Region. The second initiative was Cinde, founded in October 1982 by prominent businesspeople and financed by USAID grants within the CBI program, which we describe in more detail below.

Baxter entry in 1987. Baxter's first contact with Costa Rica was through an executive who visited the country as a tourist, and this happened at a time when Baxter was concerned with the potential disruptions that hurricanes could cause to its operations in the Caribbean (Cornick & Trejos, 2018). Close to the US but not subject to the impact of hurricanes, Costa Rica became a candidate as an investment destination. And was eventually chosen after the corporation conducted a series of studies on countries that offered lower costs and had a strategic location for the distribution of Baxter's products.[15] Costa Rica's proximity to the US, Dominican Republic, and Puerto Rico created logistical synergies for Baxter manufacturing operations. Baxter pioneered to invest in Costa Rica in a period when the country was undergoing a process of trade liberalization, but before Cinde prioritized the medical devices sector and before the current FTZ regime.[16] No new medical devices investments took place until 1991, one year after the Export Processing Zones were reformed into the FTZs regimen of 1990.

The existence of an "aggressive, effective and knowledgeable foreign investment promotion agency" with a successful high-tech FDI attraction strategy that have built confidence among global investors. Cinde was founded in October 1982 as a non-profit investment promotion agency, supported by the Costa Rican government and financed by USAID grants within the CBI program. Cinde accompanied and supported the beginning of the transition to the new export promotion model. Its broad mission was to help in the development of the economy, but through time, Cinde gained very relevant expertise for FDI attraction.

While there is no paper studying the counterfactual scenario of FDI attraction without Cinde, the literature using Costa Rica as a case study have highlighted Cinde's positive role in FDI attraction. Spar (1998) highlights Cinde as a facilitator and a coordinator in Intel's site selection process. One of the factors that made Intel choose Costa Rica for the location of its plant was "the existence of an aggressive, effective and knowledgeable foreign investment promotion agency like Cinde" (Rodríguez-Clare, 2001, p. 316). Alfaro (2024) refers to Cinde as "a significant driving force" in attracting FDI in the medical devices industry; Román et al. (2014, p. 29) characterizes Cinde as

against communism. And the US sought to combat the expansion of communism in the region through various economic aids, from which Costa Rica took advantage as the oldest democracy in the region.

[15] See https://www.nacion.com/economia/baxter-planea-expansion/LT6JJVP3PRFDPP37V2JD4QJJNE/story/ visited on March 15, 2024.

[16] For a more in-depth description of Baxter activities in Costa Rica see Abbate et al. (2010) and Bastos-Vega et al. (2022).

a “high-performance organization”; and Cornick and Trejos (2018) highlights Cinde’s role as a success story of a productive development strategy.

The existence of strong and growing demand attracts OEM foreign suppliers to set up operations in the country. The growth of the sector and the presence in Costa Rica of some of the top global manufacturers, along with the increased volume and complexity of their operations and the sector’s strong growth prospects, attracts foreign suppliers to set up operations in the country. OEMs also push their global suppliers to co-locate close to its production sites; a practice known as follow sourcing (Humphrey, 2003).

Overall, the decision of the early medical devices company to choose Costa Rica as a destination can be explained by demand-seeking and “efficiency-seeking strategies of multinational MDs-led corporations of US origin” (Bamber & Gereffi, 2013, p. 35); a stable democracy with relatively good quality of life; a good investment climate, including a strong tradition of peace and democracy and high standards of intellectual property protection. Commitment to protecting natural resources, sustainable environmental policies, and energy from almost 100% renewable sources. Stable policies, with continuity and strategic vision adapted to changing global conditions regarding foreign trade, investment attraction, and export promotion led by the three key institutions: Comex, Cinde, and Procomer.

Evidence from press releases. As can be seen, many factors explain the country’s success in attracting high-tech FDI. To help test the hypothesis raised in the Costa Rican case studies, we built a database of newspaper articles with the company’s reason for investing or reinvesting in the country. We summarize the results in Table 2, which shows that the most frequently cited reasons are related to "human talent," followed by "strategic location" and "education." Human talent is a category that embodies the workforce’s quality, availability, specialization, and soft skills. Education is a category that refers to educational standards, technical knowledge, and qualifications, including being bilingual. Strategic location is related to the country’s geographic proximity to the US. Another relevant reason is the country’s economic and political stability, which creates a trustworthy environment for companies to make investment decisions, and the country’s sustainability features, including Costa Rica’s commitment to environmental policies and the promotion of renewable energy. Infrastructure and competitiveness are mentioned less frequently, hence highlighting the importance of improvement in those areas.

Regarding strategic location, Costa Rica has an innate strategic location in relation to the United States, sharing the CST time zone and being just three to four hours away by plane from major cities like Miami, Houston, and Atlanta. Moreover, it has a mountain range that protects the capital and metropolitan area from direct hurricane impacts. The country also has direct and close access to ports in both the Pacific Ocean and the Caribbean Sea. Additionally, "Costa Rica’s strategic location as a connector between North and South America provides manufacturers with direct access to both markets" (Alfaro, 2024).

Comparing the reasons provided by companies with those suggested by the literature we see that both mention Costa Rica’s strategic location, economic and political stability, consolidated medical device cluster, and education as important features in choosing the country as a destination. Yet, there are also differences. The literature emphasizes the role of human talent less than the role of education, but this is not the case for companies. The literature also highlights Cinde as crucial in the development of the industry, but companies did not cite Cinde as a direct reason for investment. Additionally, the influence of the Free Trade Zones is also not mentioned by companies. Perhaps Cinde and the Free Trade Zones are undoubtedly important at an earlier decision-making stage when companies are selecting countries.

5.2 A shift in the strategy of the foreign investment attraction agency from sectorial to supply chain helped to secure the entry of key suppliers allowing to thrust the domestic value added

Strategic suppliers of medical device firms have also started setting up their operations in Costa Rica since 1991, helping increase the domestic value added by creating locally additional backward linkages and by creating forward linkages, e.g., the entry of sterilization firms allowed devices to exit Costa Rica straight to the buyer with the highest value-added. The entry of suppliers is partly explained by the existence of strong and growing demand, as explained above. But there was a second driver too, well explained by Cornick and Trejos (2018), Cinde's creation of its After Care Division.

Cinde during the 1980s directed this expertise mainly towards agriculture and unskilled intensive manufacturing sectors, especially apparel maquiladoras (after all, Costa Rica was recovering from a 12% unemployment rate during 1982). But eventually, Cinde realized that the country was losing competitiveness in unskilled-labor-intensive industries to other members of the CBI and also due to the prospects for Nafta, which would give Mexico better access to the US market than the CBI members (Rodríguez-Clare, 2001). Cinde decided to focus on sectors that were a better match for Costa Rica's relatively high education levels, including electrical, electronic, and telecommunications. These sectors not only required more skilled workers but were also experiencing fast growth in the US and strong competitiveness pressures were forcing companies to search for low-cost locations around the world. It was thought that these sectors were a particularly good match for Costa Rica not only because of its good supply of technicians and engineers at relatively low cost but also because of the widespread knowledge of English, the country's well-known political stability and democracy, as well as developed legal system and low levels of corruption. There was also a high quality of life, with good access to health services, nightlife and cultural amenities, and natural resources.

Cinde's high-tech FDI strategy emerged naturally after the entry of electronic giants like DSC Communication Corporation in 1995 and Intel in 1997, confirming that "attracting high-tech multinationals was feasible and potentially effective as part of Costa Rica's development strategy" (Rodríguez-Clare, 2001, p. 317).[17] Additionally, a FIAS study in 1996 found that "there is a basis for substantial expansion of foreign direct investment in the electronics industry in Costa Rica… Such products draw heavily on the main advantage that Costa Rica has to offer the world electronics industry: a labor force that is relatively well educated in relation to its cost." Spar (1998, p. 14) also mentions "a very well educated low wage labor pool. This is a central and critical

[17] For a detailed examination of Intel's site selection process see Spar (1998) and Rodríguez-Clare (2001).

distinction." By 1998, Cinde stated its objective to position Costa Rica as "the emerging electronics manufacturing center in the Americas."

In the following years, additional research led Cinde to include the medical devices sector among its targeted sectors. Again, just as had happened earlier with the electronics sector, success came early, this time in the form of the decision by Abbott Laboratories to establish a sophisticated $60 million manufacturing plant in the country in 1998 and Baxter's decision to expand its presence in the country with a $30 million investment.

Two key organizational changes occurred that eventually led to the service model that allowed Cinde to identify the need and opportunity to establish sterilization services for the medical devices industry. First, budget cuts in 2000 led Cinde to transition towards a sectorial specialization, which enabled the organization to build an in-depth knowledge of the sectors on which it focuses, and of the needs and requirements of companies operating in those sectors. Sector specialists plus a Business Intelligence Unit ensure that when Cinde approaches a company, it knows everything it needs to know to make a convincing case for investment in Costa Rica.

Second, in 2008, Cinde created an After Care Division to facilitate the installation and start-up of operations of firms that decide to invest in Costa Rica, and to look after their needs once operations start. The After Care Division ensures that Cinde knows what that investor needs in order to prosper in Costa Rica and to expand and upgrade its operations. The Division identifies opportunities for local and foreign suppliers to operate in Costa Rica and facilitate agglomeration economies and spillover effects.

According to Cornick and Trejos (2018), it was the combined skills of sector specialists, business intelligence, and after-care services that allowed Cinde to identify the need for sterilization services and the impact of those services in terms of the sector's costs, competitiveness, and potential for expansion. This way, an opportunity was identified: while the medical devices sector was thriving, there were no sterilization services in Costa Rica. This imposed a cost on all companies operating in Costa Rica, as production had to be sent for sterilization elsewhere, increasing inventory costs and extending the production cycle. Moreover, lack of sterilization services prevented the installation in Costa Rica of distribution centers and the logistics and marketing functions that can be associated with them.

Working in cooperation with manufacturers already operating in Costa Rica, Cinde mapped the sterilization industry and set out to systematically approach the companies in it, one by one, and convince at least one to open a plant in Costa Rica. This strategy resulted in Steris (originally knew as BeamOne) opening its electron-beam sterilization plant in 2008. Between 2010 and 2011, Steris opened a second electron-beam sterilization operation as well as an ethylene oxide operation. In 2010, Sterigenics, another sterilization provider, started offering its services in Costa Rica.

Today, Cinde regularly approaches not only firms that are the ultimate target of its effort to attract business to Costa Rica, but also their key suppliers. The aim is to anchor the investments, as the costs of moving an operation from one location to another are higher if there is a well-developed supply chain in the first location. Cinde also actively promotes changes to the investment climate to align it to the needs of the companies installed in Costa Rica.

While the establishment of sterilization services made the medical devices firms operating in Costa Rica more competitive, perhaps the most important impact was that it made the country more attractive to new firms not previously established in the country and allowed them to undertake more ambitious operations. This hypothesis is validated by the large number of new firms that have opened plants in Costa Rica since 2008 and the complexity of their operations, as in the case of St. Jude Medical and Abbott Vascular (Crespi et al., 2014, Box 9.4). The entry of the sterilization firms is also an example of Cinde's successful role in red tape advising for FDI attraction. Sterilization, particularly ethylene oxide sterilization, produces chemical waste that could potentially affect human health. According to KII, Cinde had to coordinate with the Ministry of Health for the sterilization suppliers to obtain a health permit. This coordination also allowed other OEMs to build sterilization plants, for example, Baxter opened one in 2008 and also required health permits. KII also mentioned migration permits for foreign workers and building permits with the local governments as examples of red tape advice.

5.3 The development of specialized skills and talent needed by the medical devices industry facilitated upgrading towards the production of more complex devices

The local availability of human capital with specialized skills and talent needed by the MD industry (see Table A.5) has enabled increasing the complexity of the MD manufactured. The quality of the human capital involved in production is essential to MD business success because MDs is a highly regulated industry due to the fatal consequences of human error and the potential for liability suits. Yet, there has been an increase in the complexity of the MDs manufactured in the country, where local manufacturing of Class III products has increased, indicating a growing confidence in the capabilities of Costa Rican plants to follow strict regulatory protocols.

How has the human capital in Costa Rica been accumulated? While initially firms like Baxter had to train their workers from the ground up, later plant operators and managers in the MD industry were recruited from the electronics sector, of which some were trained by Intel. Initially, medical device companies hired blue-collar workers from other industries (garment and electronics) and bore training costs. The supply of white-collar workers, such as engineers, came from the academy and the industry itself.

According to the MD Cluster Costa Rica, there is good availability of junior to mid-level, trained in public and private universities (with varying quality among the latter). However senior-level talent is more limited and related to Baxter and Intel's former workers. The country has enacted continuous efforts to build technical abilities that complement training funded by MD companies (one- to two-week induction training and constant on-the-job supervision and development). The country has enacted these efforts by coordinating efforts of secondary and post-secondary educational institutions funded publicly (including technical high schools of nine years of primary and secondary plus three years of technical education, the *Instituto Nacional de Aprendizaje INA*, *Instituto Tecnológico de Costa Rica TEC*, and *Universidad de Costa Rica*) and complemented by the private sector. For example, technical high schools offer degrees needed by the MD industry.

The INA now offers a one-week introductory course to the medical devices sector, covering good manufacturing practices, working in cleanrooms and documentation. Since 2014, the TEC offers a master's degree in medical devices jointly with the University of Minnesota and the University of Zaragoza.[18]

In addition to training human capital, a tangible benefit that has emerged over the last 15 to 20 years of sustained growth in the MDs industry in Costa Rica lies in a significant knowledge transfer due to the presence of several leading global MD manufacturers and a unique generation of specialized talent that peer countries do not have. In 2011, the industry employed approximately 12,500 people (Bamber & Gereffi, 2013, p. 42). By 2015, 19,328 people were working in the MD industry, and by 2023 there were 55,699. Labor mobility between MD firms in the country has increased the availability of local human capital with specialized skills and talent needed. Companies that settle in Costa Rica can quickly access experienced workers, facilitating new companies' rapid assimilation of advanced practices and knowledge, and shortening the learning curve for implementing advanced processes.

The current context presents unique advantages for companies interested in manufacturing more complex MDs, e.g., Class III or capital equipment, in terms of finding specialized talent in the local labor market. Unlike in the past, when acquiring qualified professionals turned to academia or other industries, today, companies can tap into a talent pool with experience in the MD industry. This evolution has shortened the learning curve of training new professionals.

5.4 Productive development programs helped linkages emerge between MNEs of medical devices in Costa Rica and local firms.

The creation of additional linkages increases the domestic value added embodied in gross exports by producing domestically a larger fraction of the value added that is being exported. To increase the domestic value added in exports, it should not matter whether the linkage is between a domestic firm, or a foreign firm established in Costa Rica. However, the literature has separately analyzed each type of firm. For example, Monge-González and Rivera (2022) characterizes the linkages between local suppliers and multinational companies (MNCs) in the medical device sector. Using 2008 to 2019 as the study period and data from the Central Bank of Costa Rica on productive chains for the medical device sector, they confirm that linkages between OEMs and

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[18] Around 136 public technical high schools (nine years primary and secondary, plus three years technical education) located around Costa Rica offer degrees needed by the MD industry. The degrees include industrial electronics (2,988 graduates), administration (2,868), precision mechanics (1,418), among many others.[18] Additionally, MD firms have worked with the Instituto Nacional de Aprendizaje (INA) to train line operators, material handlers and technicians. INA now offers a one-week introductory course to the medical devices sector, covering good manufacturing practices, working in cleanrooms and documentation. While the program now has 564 graduates, it is unclear how often it is offered. Private institutions, like SMD, also offer educational programs. Since 2014, the Instituto Tecnológico de Costa Rica (Tec) offer a master's degree in medical devices jointly with the University of Minnesota and the University of Zaragoza. By 2023, there were around 120 students graduated with this master's degree across nine cohorts. Regarding the supply of professional engineers and microbiologists, graduates in these careers have increased since 2014 and the supply is almost equally split between the public sector (of which Tec and Universidad de Costa Rica are the most important) and the private sector. Data on graduates comes from Hipatia.cr available at https://hipatia.cr/dashboard/talento-tecnico accessed April 5, 2024.

domestic firms are taking place and maturing. Local purchases by MNEs of medical devices in Costa Rica have increased from 7% to 16% of the total value purchased (both in Costa Rica and abroad), of which 58% correspond to purchases from domestic firms (fluctuating between 53% and 65% over the period analyzed). The value of local purchases has multiplied eightfold in that period.

Grupo Vargas (GV) was often cited in our interviews (and often cited by newspapers) as a success story in terms of generating new backward linkages.[19] GV invested continuously during five years "until we were able to convince Allergan that we were capable of printing locally what they were importing from their suppliers abroad" mentioned Marco Vargas, commercial manager of GV, during an interview to a local TV show.[20] These investments included certifications, specialized quality control equipment, procedures, and certifications of good manufacturing practices.[21]

Some linkages with MNCs of medical devices in Costa Rica can be partially explained by the existence of public policy and the involvement of the private sector to promote linkages. A comparative study (Morales-Sandova et al., 2019) analyzing eight cases of the medical equipment sector in Germany and Costa Rica found that German suppliers generated linkages through already existent networks within the sector that help link MNCs with suppliers, where MNCs participate in different clusters of a specific sector that facilitates linkages between suppliers. Costa Rica, on the other hand, the study says, have institutions that help link local suppliers with MNCs and the extent to which these policies successfully generate and promote linkages depends on the support provided by the institutional ecosystem.

In 2019, the Medical Devices Cluster Costa Rica, a private, industry driven, initiative rolled out, bringing together MD companies with operations in Costa Rica with the aim of articulating efforts, creating synergies, and fostering co-creating spaces that allows Costa Rica to keep strengthening and developing the MD Ecosystem. One of the five priority areas of the Cluster is developing local suppliers and supporting productive chains.

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[19] See, for example, https://www.nacion.com/economia/negocios/grupo-vargas-reconvirtio-su-imprenta-para-vender-a/6C5JAHC3XJBBVDFXDPCQBNNPIE/story accessed

[20] See https://www.youtube.com/watch?v=qFl8I5sx3I0 accessed

[21] Grupo Vargas (GV) is a family firm started in 1941 as a small printing office for local newspapers that eventually became the biggest labels press in Costa Rica by selling to MNCs in the food and beverage sector, especially beers and pineapples, and later diversified to thermoforming and folding boxes. GV realized that MD MNCs in Costa Rica were importing the printed materials (instruction books, labels they require, the folding boxes where the product goes, etc.) from their suppliers around the world. "We spent the next five years investing until we were able to convince Allergan that we were capable of printing locally what they were importing from their suppliers abroad" mentioned Marco Vargas, commercial manager of GV, during an interview to a local TV show. These investments included certifications, specialized quality control equipment, procedures, certifications of good manufacturing practices, that require everyone entering the plant to take off their watch, earrings, rings, protect themselves from their hair, so that no one product that is leaving the plant (even if it is a brochure, an instruction brochure, a folding box, or a thermoformed packaging) has a hair, "this would be terrible for these companies where there is no margin for error, the product must be 100% good, and that takes getting used to. It is a whole culture that must be acquired in companies." Today, Grupo Vargas has a manufacturing plant in the FTZs Multiplx in Coyol, Alajuela and is a supplier to the most important global companies installed in Costa Rica that produce all their literature.

Additionally, in 2003, Costa Rica launched a productive development program (PDP) known as Costa Rica Provee (a program that promotes backward linkages between MNCs and local firms) that was later transformed into the Linkages Division of Procomer. According to Cornick and Trejos (2018), the role of the Linkages Program gradually evolved from generic to industry-focused linkage promotion, and from matchmaking to business development. While Procomer initially had simply identified local capabilities and then tried to match them to the demands of multinationals operating in FTZs, since 2010 Procomer started identifying MNCs' needs, then surveying local capabilities. If such capabilities were lacking but developing them was deemed feasible, it worked with potential suppliers to do so and in cooperation with a large set of other public institutions organized under an Inter-Ministerial Linkages Commission with private sector and academy participation. This coordination was important as the task of developing suppliers clearly was beyond what Procomer could do by itself. Wide policies were needed to achieve these new policy goals, and the context at the time was favorable to achieving broader policy coordination. The new strategy was explicitly demand driven and focused the Linkages Program exclusively on tradables, with a special focus on high-value-added linkages.

While Costa Rica Provee was successful in promoting new linkages and creating new exporters from local SMEs (Rodríguez-Álvarez et al., 2013), to this day most local purchases by MNCs are unrelated to public policy efforts to promote them—according to Cornick and Trejos (2018) and our KII.

6. Main bottlenecks that have held back movement into higher value-added segments

6.1 Cultural barriers and informality are restricting backward linkages between medical device multinational corporations and domestic companies.

Although local purchases by MNEs of medical devices in Costa Rica have increased, the literature suggests that linkages between medical device OEMs and local companies are limited (Bamber & Gereffi, 2013; Cornick & Trejos, 2018; Gereffi et al., 2019; Monge-González & Rivera, 2022).

Monge-González and Rivera (2022) also differentiate between specialized inputs (that do become part of the final product or service and, therefore, of the GVC), non-tradable services (i.e., maintenance services, electricity), and standardized inputs (i.e., generic ones such as packaging materials). They do so because it is through specialized inputs that it is possible to scale up the GVC, increase the domestic added value of exports and further enhance productivity spillovers to domestic supplier companies. They find that local purchases of specialize inputs by medical device multinational corporations represent just less than 2% of the total purchases. Moreover, the relative importance of domestic suppliers has decreased from 76% to 47% vis a vis an increase in the weight of foreign providers in Costa Rica. Regarding sales of specialized inputs by domestic suppliers to MNEs of medical devices in Costa Rica, 75% correspond to distribution services of medical articles, orthopedics, specialized textiles and equipment of various kinds, followed by 15% of wholesale trade of medical articles.

According to Cornick and Trejos (2018), significant, albeit low-value-added linkages between local companies and MNCs developed spontaneously. MNCs inevitably purchase nontradables locally, including cleaning services, food, security, and some logistics, as well as the supplies required to provide such services. Likewise, MNCs will necessarily buy water, electricity, and telecommunications services from local suppliers and in some cases, they are likely to purchase packaging materials locally as well. What did not happen spontaneously was the development of significant linkages in tradable goods and services that would have involved local companies gradually climbing up the value chain and providing increasingly complex, knowledge-intensive inputs, parts, finished products and services to MNCs (Cornick & Trejos, 2018).

Why do linkages remain insufficient (or at least that is the perception) even if PDPs and a Cluster initiative are supporting their creation? From the Medical Device Cluster Costa Rica perspective, the main challenge for generating more backward linkages is that local providers need to have robust, equivalent, and comparable quality systems. Yet, quality systems are underused in Costa Rica. Most of the sales take place in the national or regional markets where no certification is required, and firms are not used to follow processes and norms or keep records of the suppliers. Informality among firms is common in Costa Rica, where highly productive firms that generate well paid jobs coexist with low productive firms that generate low quality informal jobs. While there are no studies for Costa Rica, an article points out that 10% of the population of informal firms in Brazil could be able to jump the threshold of minimum capacities to participate in a dynamic value chain.[22] In this sense, firms interested in becoming suppliers for an MD MNC must adapt, and the cluster recognizes that this comes with a learning curve and a change in culture. “It is a process of learning and support. Any company needs an adjustment process to become suppliers”—says the president of the Cluster.

Safety regulations push MD firms to be a particularly demanding sector in terms of quality checks, and MNCs usually must work backwards with suppliers to have in order many of the paperwork that might eventually be asked by the FDA, for example. While an ISO 13485 or a GMP certification is not always needed by MNCs participating in the MD industry in Costa Rica, these MNCs do require a chain of good practices and operational excellence from suppliers that allows them to demonstrate that the supplier they are working with is suitable for that specific product. This means keeping electronic quotes to provide materials traceability, quality standards for materials and products, etc. When certifications are required, suppliers often see the certification system as very cumbersome or very onerous. Sometimes internal organizational changes must be implemented or specialized software must be purchased to keep track of decisions and acquisitions along the supply chain.

Another explanation is the limited supply of MNC-ready local suppliers (Cornick & Trejos, 2018). In some cases, technical capabilities may be lacking. In others, the binding constraints can involve questions of scale, availability of finance, willingness to incur risks, or lack of general quality certifications and/or sector-specific and relatively costly certifications. Additionally, the availability of qualified personnel at competitive salaries seems to be an increasingly significant constraint.

Unfortunately, these constraints on creating more linkages cannot be alleviated by investing more money in the Linkages Program, but rather through long-term, broad policies that address both

[22] See https://www.crhoy.com/opinion/confrontando-la-informalidad-y-el-dualismo-productivo-en-costa-rica/ accessed

the demand and the supply side of local (tradable) goods and services (Cornick & Trejos, 2018). The Cluster and *Academia de Centroamérica* point to another element, the design of the PDPs itself. Procomer offers over ten PDPs one of which, Programa Crecimiento Verde, provides non-refundable funds and technical guidance for micro, small, and medium-sized businesses to obtain certifications or to implement changes in the production process.[23] The *Sistema de Banca para el Desarrollo* (SBD) offers loans and targeted financial services to companies typically underserved by traditional banking institutions such as small and medium-sized enterprises (SMEs), entrepreneurs, and sectors such as agriculture, tourism, and innovation. SMEs could potentially use SBD to obtain certifications. Yet, "successful suppliers of MNCs in the MD sector in Costa Rica are often from medium to large companies" mentioned the Cluster president. GV, for example, was a medium firm when it started supplying to Allergan. The local legislation (*Reglamento a la Ley de Fortalecimiento de las Pequeñas y Medianas Empresas, Ley N° 8262*) establishes thresholds for the classification of companies by size based on the company's assets, annual sales, number of employees, and economic activity. "One option is to relax the threshold to allow more companies to be classified as an SME" mentioned Ricardo Monge in the interview. The Government could do this without needing Congress approval. "The mistake we are making is that we are penalizing companies that have managed to reach a certain size and there are no public programs to which they can apply to obtain financing or other types of support so that they can chain themselves." Apparently, all the pieces of the puzzle are there but someone must put them together. From his perspective, a coordinating body using a cluster approach to value chains should be responsible to do it (Monge-González, 2018).

It appears from the experience of Costa Rica that promoting backward linkages is a pending task. "If it is not possible to develop a local supplier, that FDI supplier will eventually arrive in the country" mentioned a KII. One example is GV, who offers thermoformed services but not to the medical device companies because there are other foreign firms in Costa Rica offering such service (that is why they specialized in IFUs printing and packaging). Another example is coatings. A coating of Teflon or a hydrophilic material (which becomes slimy if it touches a liquid), is used in most devices that are insertable. There was no coating supplier in Costa Rica. Yet, the need was met as FDI. Precision Coating entered in 2012, and Specialty Coating Systems entered in 2015. While developing a supplier from scratch is a different story than supporting a firm to make the jump to become a supplier of an MNC, it is worth asking why Costa Rica did not have a coating firm despite the need.

6.1 Skill shortages persist, and more bilingual STEM graduates are needed to continue growing in the manufacturing and assembly stages

KII mentioned the need for additional bilingual graduates in the areas of science, technology, engineering, and mathematics (STEM). Bilingualism is essential (investment primarily comes from the US and Europe after all), but an analysis of the local labor surveys shows that only 1/4 of college or university graduates talk and write in English in the last quarter of 2023.[24]

[23] See https://www.procomer.com/exportador/programas/crecimiento-verde/ accessed

[24] This percentage has fluctuated over time between 23% and 36% with a downward trend. Also see Figure A.11.

There are supply and demand side challenges in the formation and retention of human capital for innovation amid the linkage of the industry with academia and other research stakeholders. On the supply side, public universities enroll most freshmen in the country, but a particular concern is their inertia toward social science and humanities careers. Figure A.12 shows that there have been fewer freshmen enrolled in STEM careers than in non-STEM careers. While the difference is not relatively large, it seems from the declarations by KII that the numbers should be more skewed toward STEM. The OECD has noted that the education system has not kept pace with ongoing structural transformation towards high technological- and skill-content sectors, resulting in skills shortages despite the high levels of unemployment (OECD, 2018). The OECD also highlighted the need for significant tertiary education reforms given that Costa Rican public universities have a high level of autonomy and few incentives to respond to labor market needs (OECD, 2018). The small number of STEM graduates poses a significant obstacle to Costa Rica's ambition of developing a more high-technology, knowledge-intensive economy (OECD, 2016, 2017, 2018). Why are more freshmen in non-STEM than in STEM careers? According to the KII, this is partly because opening additional spots in some STEM careers is expensive (for example, in engineering which requires installing expensive equipment in new laboratories), but also because few students are seeking a STEM career.

On the demand side, students seem to prefer other fields of study rather than STEM careers, and this is also limiting public universities from opening additional spots in STEM. Students might not be interested in pursuing a career in STEM just because of personal preferences, or perhaps due to a lack of information on prospective income dynamics. In this sense, the MD sector has not been transparent enough by providing comprehensive and systematic information about employment opportunities, including wage levels and potential career paths. Making available this information could nudge people to study English and have a STEM career.

Increasing soft skills, the share of English-speaking workers, highly specialized profiles in regulatory areas, and post-graduates is a priority for MNCs. The lack of skills in crucial areas such as technical problem-solving, process improvement, and communication is a central concern for companies[25]. The absence of competencies in project management and economic analysis, or financial engineering, has also become a prominent obstacle, marking key areas that require attention and development. Additionally, companies increasingly indicate English skills as a fundamental requirement for their workers. Since investment primarily comes from the United States, Canada, and Europe, bilingualism has become essential.[26] The need for highly specialized profiles, especially in regulatory areas, is an additional challenge. The lack of training in regulatory issues and the shortage of specific skills in clinical research exacerbate the gap between the current academic offerings and industry demands. This mismatch is accentuated in emerging areas of the industry, such as project management and economic analysis, which currently lack specialized training. The absence of master's and potentially doctoral programs in STEM disciplines hinders progress towards research and development. Closing these gaps requires

[25] Interview with a representative of MNC located in Costa Rica
[26] Interview with FDI attraction organization

significant investment in specialized academic programs that meet the changing demands of the industry and foster the growth of the human capital necessary for innovation in MDs.

7. The life cycle of new medical devices and opportunities for local firms.

During the research and product development (R&D) stage, new products are conceptualized, prototypes are produced and tested, and potential manufacturing capabilities are assessed. Below and in Figure 4, we describe in more detail each of the R&D phases based on Gelijns (1989) and WHO (2010) to identify opportunities where local firms could participate further.

7.1 The life cycle of new medical devices

Invention of a new device. Innovations are generally categorized into two broad groups, radical and incremental, and this is also the case for medical devices. The invention of medical devices is often incremental rather than radical. Radical innovations usually require large-scale investments in research and development due to their resource-intensive nature, which is why radical innovations typically occur in large firms. But usually, small firms and individuals produce most of the innovations in the early stages of developing a new class of medical devices, and larger firms play an especially important role later on in the development process (sometimes through the acquisition of small firms). In this sense, biomedical, clinical, and bioengineering research provides an important contribution to the knowledge base underlying medical device development. Physician-researchers also play an important role in the invention of medical device prototypes. Not only do they identify the clinical need for a new device or for improvements in existing devices, but they may also be the innovators and builders of the original prototype.

File for a patent. A patent application may be filed after a product is invented. Yet, the value of patent protection in medical device development is less evident than in the pharmaceutical R&D process. In the device area, it is easier to invent around a patent, and the research and development time is shorter (10 to 15 years in drugs and three to seven years in devices). Furthermore, large-scale investments needed by some devices may prevent competitors from entering the market.

Regulatory Approval. The development of new devices is governed by regulatory schemes which focus mainly on safety efficacy testing practices. The FDA classifies medical devices into three classes (Class I, II, and III) based on their risk and the level of regulatory control needed. Class III devices are typically those that are high-risk and require premarket approval (PMA). Devices are automatically placed in Class III unless the sponsor successfully petitions the FDA to reclassify it as “substantially equivalent” to a device already on the market, this is called a 510(k) submission. Devices may be found to be substantially equivalent only if the new technological features of a device can be shown not to decrease its safety and efficacy. This may be demonstrated through descriptive, performance, and even clinical data. If successful, a 510(k) allows sponsors to market the device without going through the more rigorous PMA process. Between 2003 and 2007, the FDA reviewed roughly 93% of medical devices through a 510(k) and 7% underwent the full pre-marketing approval process (GAO, 2009).

The PMA process, or in some instances a 510(k) submission, requires manufacturers to provide detailed scientific evidence, including clinical trial data, to demonstrate that their device is safe for its intended use. Clinical trials involve subjects (patients), an Institutional Review Board (IRB), and laboratories or physicians who carry out the clinical trials. The IRB examines the investigational plan and approves clinical studies for their institution. In addition to clinical evaluations, clinical testing usually involves an initial pilot stage and a technical testing stage. During the pilot stage, the prototype's design and materials are further developed and tested. During the technical testing stage, for example, the electrical and mechanical components of infusion pumps are subject to technical evaluations, and bench tests are performed to determine a pump's accuracy and reliability. After the technical development has become more or less stabilized, a series of safety and efficacy evaluations of the 'final' 'initial' product can begin. Based on the results of clinical investigations, a device may be approved for marketing. s

Scaling up for production and post-marketing surveillance. During clinical studies, much industrial effort may be directed towards 'scaling up' for production. The necessary production capacity may vary widely, ranging from 10 to 100,000 devices a year. Process development—that is, establishing the manufacturing parameters—takes place in conjunction with input from the engineers at the manufacturing plants to determine the most efficient means of production.

After a medical device receives PMA and is marketed, the FDA and manufacturers continue to monitor its performance in real-world settings to detect adverse device reactions. The FDA receives reports on device hazards from health professionals and manufacturers and device manufacturers are required to keep records of complaints as part of GMP regulations. During production, a team of engineers continues to improve upon the production process in a process known as *sustaining engineering*. These engineers work in close contact with the product development teams. This stage is also characterized by constant improvement to existing devices as patents expire and new substitutes enter the market. Such improvements could include material enhancements (such as using or substituting original materials for new biocompatible coatings, antimicrobial surfaces, and advanced polymers), design improvements (such as redesigning handles of surgical tools for better grip and comfort during use), usage enhancements (such as transitioning to digitally interactive IFUs or including a mobile app support), and technology advancements (such as increasing the accuracy of sensors used in devices like glucose monitors or heart rate monitors), among others.

7.2 The existence of specialized skills enabled companies to consider the country for research and product development processes

A study of 2023 by the local think tank *Programa Estado de la Nación* among 55 domestic and foreign-owned firms with different roles (OEMs, manufacturing contractors, and suppliers) found that 42% of the companies carry out R&D activities in the country.[27] This is a large increase compared to 2013, when only a small number of OEM firms in Costa Rica were performing additional manufacturing R&D focused on improving the production process (sustaining

[27] The study results are available at https://hipatia.cr/dashboard/id-stat accessed October 3, 2024. Also see https://estadonacion.or.cr/dispositivos-medicos/ accessed October 3, 2024.

engineering) and establishing the new production process for new products (process development) to be launched directly from Costa Rica (Bamber & Gereffi, 2013, p. 33). Most MD companies initially focused their presence on manufacturing activities. Subsequently, some companies invest and transfer R&D operations to Costa Rica. Such local R&D has been possible thanks to the existence of specialized engineers who graduated from academic programs with guaranteed quality and are further trained by the industry.

Furthermore, the presence of organizations with the installed capacity of laboratories has made notable advances in developing preclinical studies in MDs, including animal studies. Although local laboratories may not have specific certifications, their participation is concentrated in the initial testing phases, followed by the submission of accredited results for external certification, particularly before entities such as the FDA. An illustrative example of this progress is the collaboration between the National University and Boston Scientific, where over 40 contracted preclinical studies have been developed. This joint effort has allowed for preclinical studies even in institutions such as UCIMED, marking a milestone in the involvement of medical device companies in the country. Such collaborations demonstrate the growing capability of local laboratories and companies' willingness to outsource preclinical studies, supporting innovation and product validation in Costa Rica's medical device sector.

Establishment Labs is an exceptional example of an MD company that develops its R&D fully from Costa Rica, from prototyping to sustaining engineering. The limitations for conducting certain types of tests in the country are due to the need for laboratories to perform such analyses. The robust availability of talent and investment by companies in developing advanced technologies positions Costa Rica as an emerging player in the development and innovation of MDs.

7.3 Lack of incentives limit the ability to deepen research and development through collaborative projects between public universities and the medical device industry

According to KII from Cinde, Cluster of MD Costa Rica, and UCIMED, public universities, who publish the most in Costa Rica according to Hipatia, are “not ready for joint projects”, mentioned a KII. The academic sector is the main source of investment in R&D in Costa Rica, of which the public universities have the largest share (Monge-González, 2016, p. 94). Yet, collaboration between public universities and the business sector is scarce (OECD, 2016, 2023a). This is partly explained by the way public research is funded (OECD, 2020, 2023a). The vast bulk of funding (around 90%) for public universities comes from the government’s Special Fund for Higher Education (FEES), which totaled 1,134 million USD in 2023.[28] Despite its size, FEES does not have an attached steering, monitoring, and evaluation framework (OECD, 2018, p. 155). Furthermore, there are no centralized and independent external evaluation mechanisms (OECD, 2020, p. 60). Moving towards competitive and performance-based funding and establishing a connection with the business sector as one of the eligibility criteria could increase incentives for public universities to pursue research and innovation that benefit both the university and the MD industry. A similar observation is shared by other studies (OECD, 2020, 2023a). Additionally,

[28] 1 USD = 508 CRC. The value comes from https://semanariouniversidad.com/universitarias/asi-quedo-distribuido-el-fees-de-2024/ accessed April 5, 2024.

grants that encourage joint research projects between academia and the private sector are scarce. Overall, the absence of financial incentives that foster cooperation between companies and public universities hinders the development of joint research projects that could lead to significant MD advances in incremental innovation, conceptualization of new products, and materials, or even adapting existing medical devices for emerging markets.

Variability in public universities' internal regulations creates confusion and further limits companies' access to effective collaborations. Currently, only the *Instituto Tecnológico de Costa Rica* has regulations on spin-offs, and research hours are not consistently recognized in all cases.[29] Established limits restrict universities' ability to allocate resources to joint research, and the system is not adapted for selling research services. Efforts such as those by CONARE in harmonizing concepts and analyzing intellectual property policies aim to improve this situation (Argüello-Arce, 2021), but gaps persist.

Information asymmetries and myths also hinder collaboration between public universities and the MDs. From the business perspective, the myth is that "academia does not want to collaborate with me." In contrast, from academia, there is a fear that "companies will profit from everything I do, and I will end up losing." Although there has been a shift in universities' willingness to collaborate with the industry, significant cultural gaps persist when establishing meaningful collaborations between public universities and the MD industry. The academic and industrial sectors need greater awareness and openness to foster a culture of collaboration in which knowledge exchange and active participation are key elements.

Finally, the absence of financial incentives (grants) to foster academy-industry cooperation and few certified laboratories (e.g., with Good Laboratory Practices, GLP) restrain further linkages. The near-nonexistence of certified laboratories means that their results are not valid for FDA approval, but limited access to funding and an unpredictable level of demand also reduce the chances of investing in obtaining certifications.

A 2023 study by the local think tank *Programa Estado de la Nación* found similar reasons why companies (either OEMs, manufacturing contractors, or local suppliers, domestic or not) do not carry out R&D locally to a larger extent. For some companies, their decision to invest or not in R&D depends on the corporate decisions of multinational companies. For other companies, the MNC's strategic plan does not contemplate carrying out R&D in Costa Rica or that these activities are only carried out in (or near) the headquarters in a developed country. These are reasons for which the country has little direct margin of action.

However, there are other reasons why companies are not carrying out R&D locally for which the country could have more margin of action. Companies mentioned a shortage of suppliers with specific certifications and highly qualified talent (see Table A.5 for a list of these profiles). Furthermore, the lack of tax incentives to support investment in R&D is in stark contrast to the norm in economies of the Organization for Economic Co-operation and Development (OECD, 2023) and even in the region, where countries such as Argentina, Brazil, Chile, Colombia, Ecuador,

[29] Interview with FDI attraction organization.

Mexico, Peru, and Uruguay have implemented tax incentives to support R&D investment. In addition, Ecuador, Mexico, Peru, and Uruguay have implemented tax credits or income tax deductions that are contingent upon expenditures related to R&D or technological innovation (ECLAC/Oxfam, 2019).

The study also examined the challenges confronting companies that engage in R&D. Firstly, the shortage of human resources with postgraduate degrees and novel skills is once more identified as a significant impediment to the effective transition towards higher value-added segments. Additionally, companies have emphasized the challenges posed by the weak interconnections between them, the government and academia, and the difficulties associated with the lack of agility in carrying out procedures, including the difficulty in importing R&D inputs and the scarcity of specialized laboratories with the requisite quality certifications for this activity.

Further Opportunities for Costa Rica. There are several opportunities for Costa Rica in each of the different stages of R&D. First, local entrepreneurs in the health area and technological area can play an important role considering that most of the new medical devices are incremental innovations and small firms and individuals produce most of these innovations. Yet, Costa Rica has no local funding that promote close interactions between clinicians and the industry, and institutions doing research in the areas of biomedical, clinical, and bioengineering are quite limited. In the US, funding in these areas is also relatively small and must be complemented by private investment, but organizations providing private investment in these areas in Costa Rica is also nonexistent. An important question that arises is how to attract private investment in this area.

Procomer has been working with the ecosystem in promoting efforts to connect entrepreneurs with international funding through the *K-Global* financing platform. The organization is aiming to bring local entrepreneurs to the next level and provide them with the needed tools to develop formal investment project with an adequate accounting and financial structure so that local entrepreneurs can gain access to international funding. However, the challenge is obviously how to keep these business ideas in Costa Rica, as the incentives' structure and tax benefits push entrepreneurs to open an office in the US or other developed nations. US investors, as is understandable, prefer to play the game under US rules rather than adventure in a developing country. However, the FTZ and local taxes do not provide incentives to bring investors to Costa Rica, and instead tax them whenever they have earnings.

Second, local legal firms specializing in patent applications and regulatory approval have an opportunity as filing for a patent requires non-clinical processes and legal technical knowledge that large companies could make from Costa Rica. One important limitation, however, is the fact that intellectual property could be closely guarded by firms, and the process for filing for a patent could be carried out only in the firm's headquarters.

8. Discussion and Conclusions

In this section, we develop a strengths, weaknesses, opportunities, and threats (SWOT) analysis to further understand the factors influencing Costa Rica's MD sector.

Strengths. Costa Rica's strengths for the medical devices sector includes the presence of manufacturing giants like Baxter, Abbott, Edwards Lifesciences, Philips, Boston Scientific, and another 36 original equipment manufacturers (OEMs) and 45 suppliers that provides strategic services such as sterilization and coating. The establishment of anchor companies, such as Intel and Baxter, marked significant milestones that contributed to economic development and changed the international perception of Costa Rica. This shift facilitated the entry of other global MD giants, creating a thriving ecosystem and demonstrating a successful track record in the medical devices industry, providing a solid foundation for further growth and development.

Costa Rica's political, economic, and social stability creates a favorable environment for business operations and investment in the MD sector, which is completely risk-adverse due to fatal health consequences. Years of investing in human capital are paying off and the country's human talent and education attracts the firms to open operations in the country. Additionally, the productive development programs of the FTZ and collaborative endeavors involving Cinde, Procomer, and Comex, played pivotal roles in positioning Costa Rica in the medical device industry. Free trade agreements, especially with the US, the European Union and China, further strengthened market access. Positioned strategically in America, Costa Rica enjoys proximity to the US and a natural shield against adverse climatic events. Its strategic location creates synergies with other manufacturing plants, and facilities nearshoring opportunities.

Moreover, the country's ability to upgrade products, attract international suppliers, and offer complementary services, such as sterilization, has been instrumental in inducing functional upgrading. The efforts mainly moved forward by Cinde to fill gaps in the value chain led to the arrival of sterilization companies, marking a turning point in export capabilities, and adding significant value to the products; these capabilities helped Costa Rica with the infrastructure and capacity to effectively distribute finished medical devices to final markets. Costa Rica's strategic evolution in attracting investments beyond final production enhanced its position on the global map of finished product exports.

The presence of skilled and versatile human capital has been a cornerstone of Costa Rica's success in the MD industry. Over the years, the accumulation of experience has resulted in a pool of professionals with both technical and managerial expertise. The adaptability of talent to changing industry demands, coupled with the resilience of Latin American professionals, positions Costa Rica as an attractive destination for research, development, and innovation.

Weaknesses. Regulatory, logistical, and infrastructure capacity obstacles present formidable challenges in the successful development of bioMDs. Addressing issues such as traceability systems, operationalizing regulations for clinical trials, and establishing accredited laboratories for valid international studies are pivotal for advancing the industry; given this aspect, the industry highly depends on imported inputs, which could impact cost-effectiveness and supply chain resilience. Financial and regulatory challenges within the local companies' supply chains further highlight the need for diversified funding sources and increased awareness and support for certifying local suppliers as part of the Value Chain. The slow integration of Local Suppliers faces challenges in meeting quality standards and expanding the production capacity of these suppliers, an aspect that has been solved by attracting international suppliers for the MNC in the country.

The current rate of local academic capacity for producing bilingual STEM graduates is falling behind with the industry’s needs to continue growing. Human capital challenges, particularly in English language skills, technical problem-solving, and specialized profiles, underscore the need for tailored training to address industry demands. Overcoming information asymmetries and regulatory limitations between academia and industry is crucial for effective collaboration and knowledge transfer. The "obscurity" period from 2010 to 2015 highlighted the vulnerability of research activities, emphasizing the importance of stable legal frameworks for fostering innovation and retaining skilled professionals. To bridge these cultural divides, it is imperative to introduce economic incentives and financing mechanisms, fostering a collaborative culture that promotes knowledge exchange and active participation between academia and industry.

Local migratory policies limit the company’s abilities to hire and attract engineers and STEM graduates from other neighboring countries in response to solving the scarcity of local talent. Costa Rica does not benefit from migratory policies like Ireland do as it belongs to the European Union (EU) and migratory policies in the EU are obviously more relaxed than those in Costa Rica.

Another weakness are local R&D capabilities and environment. There are still some challenges to promoting R&D and Innovation in the country. The current Free Trade Zone regime does not have specific incentives for R&D and there are no tax credits for R&D investments. There are no financial incentives to invest in innovation and the limited seed capital and risk capital constrains the financing options for spinoffs and entrepreneurs, impeding the growth of innovative ventures. Inadequate intellectual property legislation exposes companies to risks of theft or infringement, threatening their competitiveness and discouraging innovation.

Opportunities. Following the polarization between the US and China since 2018, it seems that the biggest opportunity for Costa Rica is nearshoring, as the US will continue to lead the consumption of medical devices (van den Heuvel et al., 2018). Companies see Costa Rica as a manufacturing hub and a center for continuous development, sustaining engineering, and research and development activities. Incorporating advanced technologies in MD manufacturing showcases Costa Rica's dynamism and adaptability in addressing industry challenges. Given this, there is an opportunity to enhance manufacturing of Class III devices, Research and Product Development, and Post-Sales Services through various elements: 1- Sustaining Engineering and Process Development in R&D, 2- Exploring Incremental Innovation R&D and Conducting Clinical Trials, 3- R&D linked to adapting developed-world products for emerging markets, and 4- Offering Training, Consulting, Maintenance, and Repair services for medical devices' equipment. Other opportunities also include exporting to other markets such as Latin America, increasing the production and exports of Capital Goods, and improving distribution.

Future trends in the medical device industry could lead manufacturers to integrate devices with services and data intelligence through wearables, smart device apps, IoT, cloud-based data and analytics, and blockchain (Dalgaard et al., 2023; van den Heuvel et al., 2018). In this sense, another opportunity is far from the manufacturing process of the devices themselves and instead lies in software development, in which Costa Rica also has a relevant presence.

The lack of intersectoral coordination and defined institutional frameworks poses a significant obstacle to fully harnessing the industry's potential. Establishing a national productivity council and implementing a coordinated local supplier development strategy is essential to overcoming these challenges and fostering a more agile and growth-oriented industry. Moreover, cultural gaps between academia, the national productive sector, and the MDs industry present a critical hindrance to collaborative efforts. The absence of grants and funds for joint research projects further exacerbates these gaps. Given this, establishing partnerships with multinational OEMs presents opportunities for accessing knowledge transfer, advanced technology, specialized expertise, and global distribution networks, thereby boosting competitiveness and value-added capabilities.

Creating a robust ecosystem and the ongoing commitment to innovation and human capital development would allow the country to evolve within the global value chain. Structural challenges in investment and innovation for multinational companies and local ventures in the life sciences industry underscore the necessity of tailored incentives. This aspect could leverage technological advancements and rapid technological progress to open doors to R&D and develop novel, high-value medical devices, positioning Costa Rica to capitalize on these advancements, given the industry track record in the country.

Strengthening the innovation ecosystem and introducing targeted incentives will be crucial for the long-term success of both multinational and local ventures in the life sciences industry. Given demographic shifts, such as the aging population, the opportunity to exploit a global demand for medical devices creates avenues for the Costa Rican medical device industry to expand its exports, increase value-added, and explore new markets.

Threats. Nearshoring is an opportunity, but it could also become a threat if it promotes investments in other sectors that use similar inputs in production than the medical devices industry uses (for example, semiconductors could also use workers with similar soft skills and technical abilities, or land in industrial parks under the FTZ regimen). This could potentially create a crowding-out effect against medical devices.

Global competition in the manufacturing of medical devices in European countries, Asia, and Latin American counterparts like Mexico and the Dominican Republic poses challenges, especially regarding pricing and productivity. This stiff competition could influence manufacturing site locations in other countries besides Costa Rica. Also, the local currency fluctuations rates may lead to variations in the cost of wages, imported materials, and equipment, affecting profitability and competitiveness. This instability could make it difficult for companies to predict and manage their expenses effectively. Populism in the region, artificial intelligence, automation, and new technologies, including digital IFUs, could also threaten the country's position and linkages within the sector.

The global minimum tax introduced under Pillar 2 of the Base Erosion and Profit Shifting Project (BEPS) is based on the Global Anti-Base Erosion (GloBE) Model Rules that a jurisdiction can introduce to impose a top-up tax on the low-taxed income of in-scope taxpayers up to 15%. Costa Rica's accession to the OECD in May 2021 implies challenges to the current Free Trade Zone regime, specifically to the full income tax credit that the regime offers to certain companies. Pillar 2 could impact the financial operations of Costa Rican medical device firms because changes in tax policies may increase operational costs and reduce profitability for these companies. Not only Costa Rica and medical device companies would be affected by this OECD-promoted policy, but also other country members of the OECD and firms. Under Pillar 2, firms are subject to the global minimum tax if they have a consolidated revenue of over EUR 750 million, and if they benefit from shifting profits to low or no-tax locations where they have little or no economic activity or erode tax bases through deductible payments like interest or royalties.[30] If an MNE operates in a country where the local tax rate is below 15%, the parent country (or another jurisdiction where the MNE is headquartered) can impose a top-up tax to bring the effective tax rate up to 15%. Yet, some large countries have not yet fully enacted Pillar 2 legislation (like the US, China, India, Russia, Brazil, and Turkey), and other countries offer incentives that are consistent with global tax rules and are not seen as harmful tax practices. For example, Ireland provides a 25% tax credit for qualifying R&D activities. Countries may introduce or expand R&D tax credit schemes as a way to support innovation and technological development, while still maintaining compliance with Pillar 2. The OECD allows countries to provide R&D incentives if they meet certain economic substance and transparency requirements.

Finally, the trend of the rapid evolution of emerging technologies, such as digital health and artificial intelligence, presents a threat as it may disrupt traditional medical device markets, so given this aspect, companies need to adapt quickly to these changes to remain competitive and meet evolving customer demands. Despite these challenges, the sustained interest in R&D investment indicates the potential for growth and advancement in Costa Rica's MDs sector. Costa Rica is a player in the MD industry, contributing to its economic growth and the advancement of the global healthcare sector.

The MD sector in Costa Rica faced five enablers for moving along the global supply chain of medical devices. First, innate characteristics (a strategic location) and acquired factors (economic, political and social stability, education, human talent, and a favorable investment climate) motivated foreign investors to start operations in Costa Rica. Second, a shift in the strategy of the investment attraction agency (from sectorial to supply chain) helped secure the entry of key suppliers. Third, the development of specialized skills and talent needed by the medical devices industry helped upgrading towards the production of more complex devices. Four, productive development programs helped linkages emerge between MNEs of medical devices in Costa Rica and local firms. Finally, the existence of specialized skills enabled companies to consider the country for research and product development processes.

But the sector is also facing three main bottlenecks that are limiting its ability to continue upgrading. First, cultural barriers and informality are restricting backward linkages between medical device multinational corporations and domestic companies, even despite the existence of productive development programs. Second, skills shortage persists, and more bilingual STEM graduates are needed to continue growing in the manufacturing and assembly stages. Finally, lack of incentives

[30] These are firms whose consolidated revenue is larger than a certain threshold (EUR 750 million).

limits the ability to deepen research and development through collaborative projects between public universities and the medical device industry.

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Tables and Figures

Table 1. Upgrading Trajectories

Type of Upgrading	Description
Entry into the value chain	A new actor begins to participate in the value chain
Product Upgrading	Shift into the production of a higher-value product
Process Upgrading	Improvements in productive efficiency leading to higher productivity
Functional Upgrading	Movement to new higher-value segments in the supply chain
Chain Upgrading	Leveraging knowledge developed in one sector to enter another value chain
Geographic End Market Upgrading	The incursion of firms into new higher-value end market segments
Forward and Backward Linkages	Forward and backward linkages increases the domestic component of production.

Source: Bamber and Gereffi (2013)

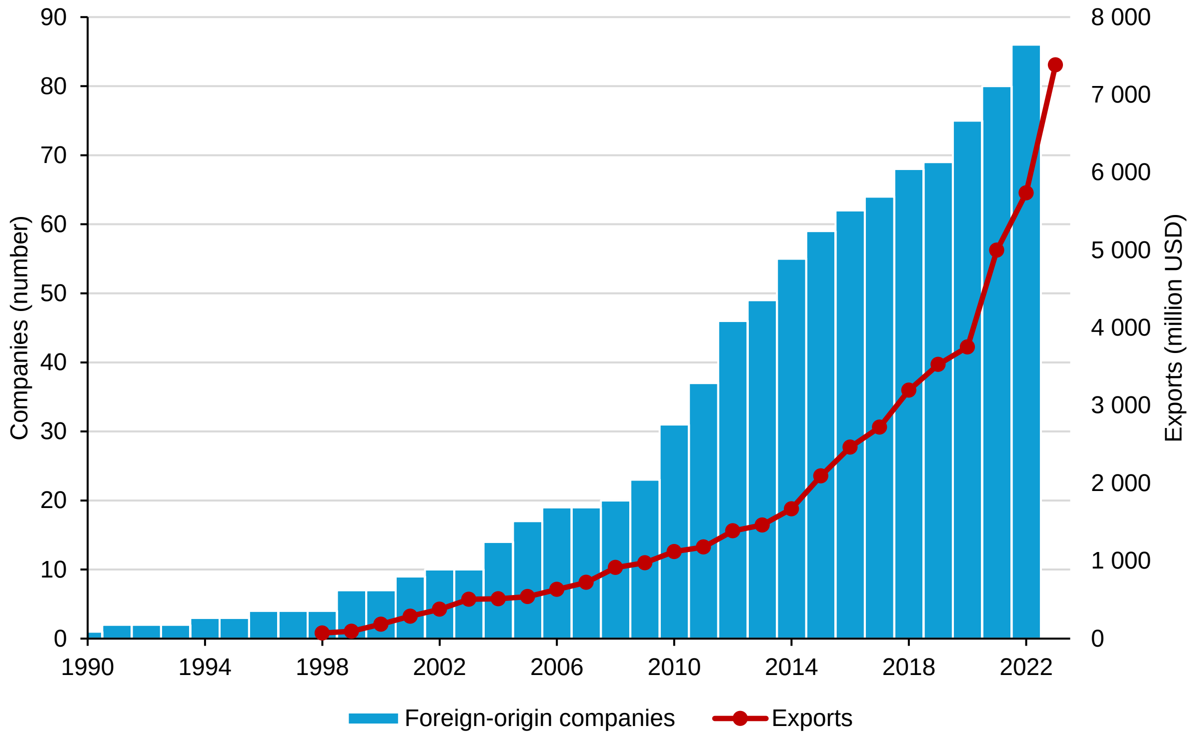
Table 2 Frequency of reasons why original equipment manufacturers of medical devices in Costa Rica mentioned for establishing operations in Costa Rica

Reason Group	Counter	Keywords
Human talent	29	Excellent workforce; quality of its professionals; exceptional quality of talent; interesting availability of talent; Human talent; talented workforce; availability of professionals with experience in medical devices; talented human resource; quality of workforce; human talent with great capacity to learn and innovate; quality of human resource; professional talent; young workforce; local talent; talented and bilingual; workforce; valuable human resource; human talent; human talent; workforce excellence; highly talented people; skilled labor; large pool of talent
Strategic location	27	Geographic location; proximity; strategic location (proximity to the U.S.); attractive geography; strategic location; proximity to U.S. and Latin American employees and customers; geographic location; location; proximity to the U.S.; strategic location; strategic location; strategic location.
Education	20	High standards of education and skilled human resource; high level of English literacy; high level of education; high level of education; skilled human resource; skilled technical personnel; highly skilled workforce; highly skilled workforce; technically skilled talent; level of education; strong education system; education; education; skilled labor force; skilled human talent; human talent with the necessary technical competencies; highly skilled workforce
Stability	14	Very stable regulatory environment; security; economic and political stability; stability; economic and social stability; stable economic conditions that the country offers; stable political environment; political, social, and economic stability; political and social stability; political stability
Cluster consolidation	13	Ecosystem; Existence of cluster; Costa Rica is a hub for medical device manufacturers; experience in medical device manufacturing; good manufacturing practices in production of MDs; experience in medical devices; cluster consolidation; existence of cluster; highly specialized local talent
Investment climate	10	Costa Rica is a country that understands and supports the medical device industry; extensive network of suppliers; solid supply chain; business conditions; ease of support; economic environment; cultural openness; investment climate; good investment conditions; economic environment.
Company's own	10	Relocation of operations; Great potential of our workers, managers, and manufacturing associates; Strategic expansion; Previous plans; Growth in demand; Increase in sales (high demand); Relocation of operations; Talented team; Costa Rican team; High demand; High demand.
Business environment	8	Business environment; business climate; Good business climate; favorable business environment; favorable business environment; business environment; favorable business environment
Sustainability	7	Sustainability policies; carbon neutrality 2030; renewable energy sources; sustainability; environmental and human rights advocacy; commitment to sustainability; collaboration and leadership in the area of environmental sustainability

Costs	4	Low cost; cost-competitive; cost; Cost-competitive environment; Cost-competitive environment
Infrastructure	2	Infrastructure; infrastructure
Competitiveness	1	Country competitiveness
Free Trade Zone Regime	1	Taxes
Linkages	1	Linkages
Security	1	Security

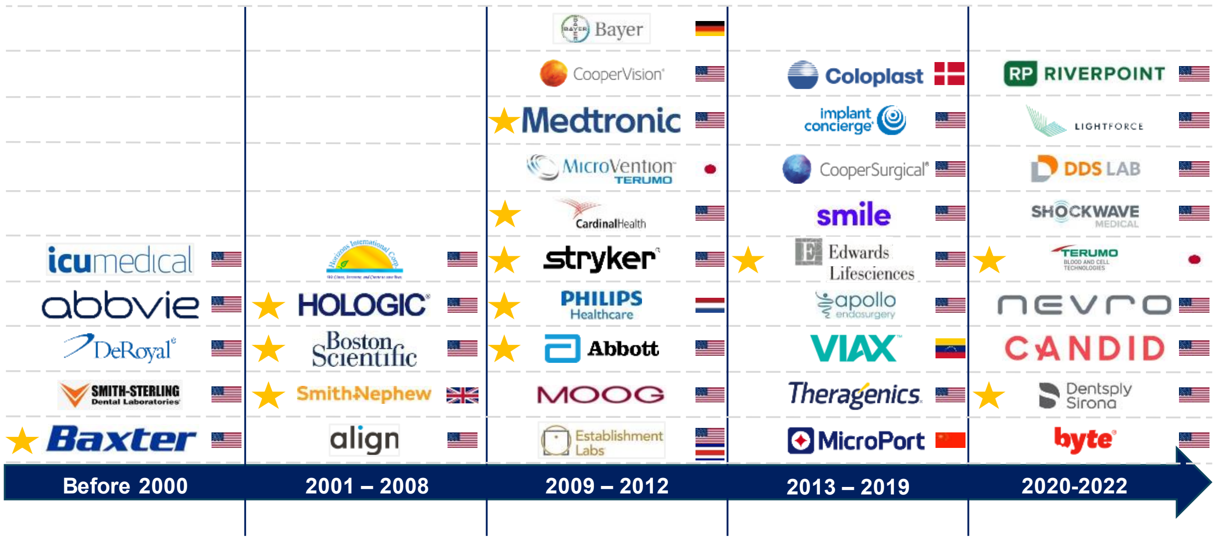
Source: own elaboration with news articles from La Nación and press releases from Cinde.

Figure 1. Number of foreign-origin firms and exports (in million US$) of medical devices in Costa Rica, 1990-2023.



Notes: exports data includes all six-digit commodity codes under the four-digit codes 9018, 9021, and 9022, plus the commodity 900130 (contact lenses). Source: own elaboration using data from Procomer (http://sistemas.procomer.go.cr/estadisticas/inicio.aspx) and Cinde.

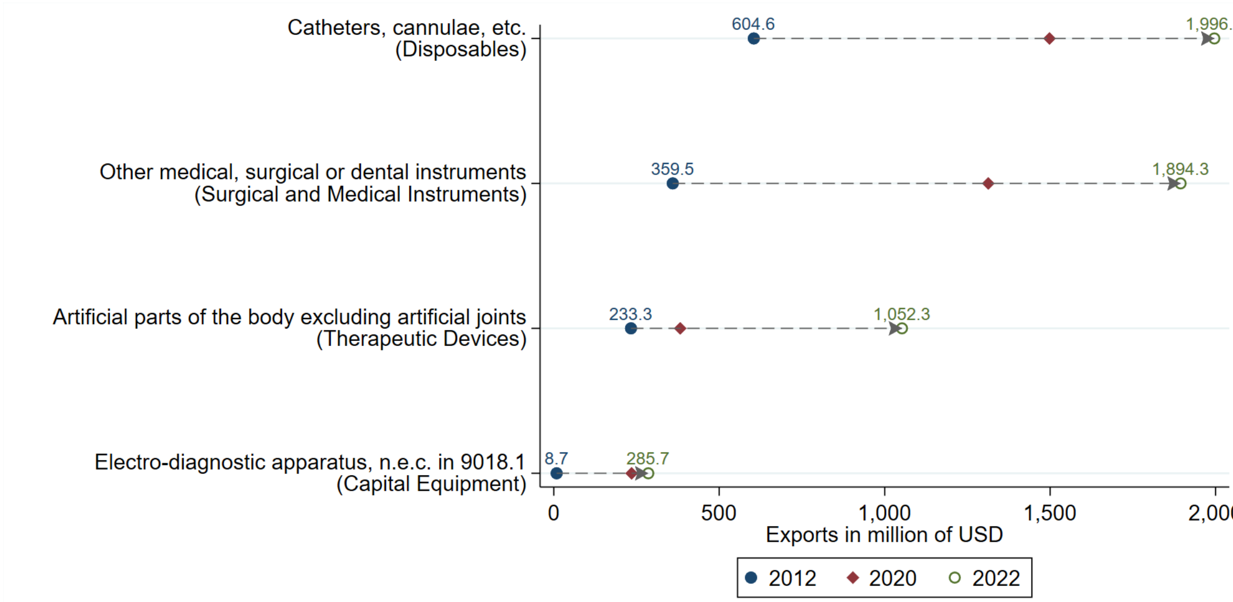
Figure 2 Entry of selected companies to the Costa Rican medical device industry



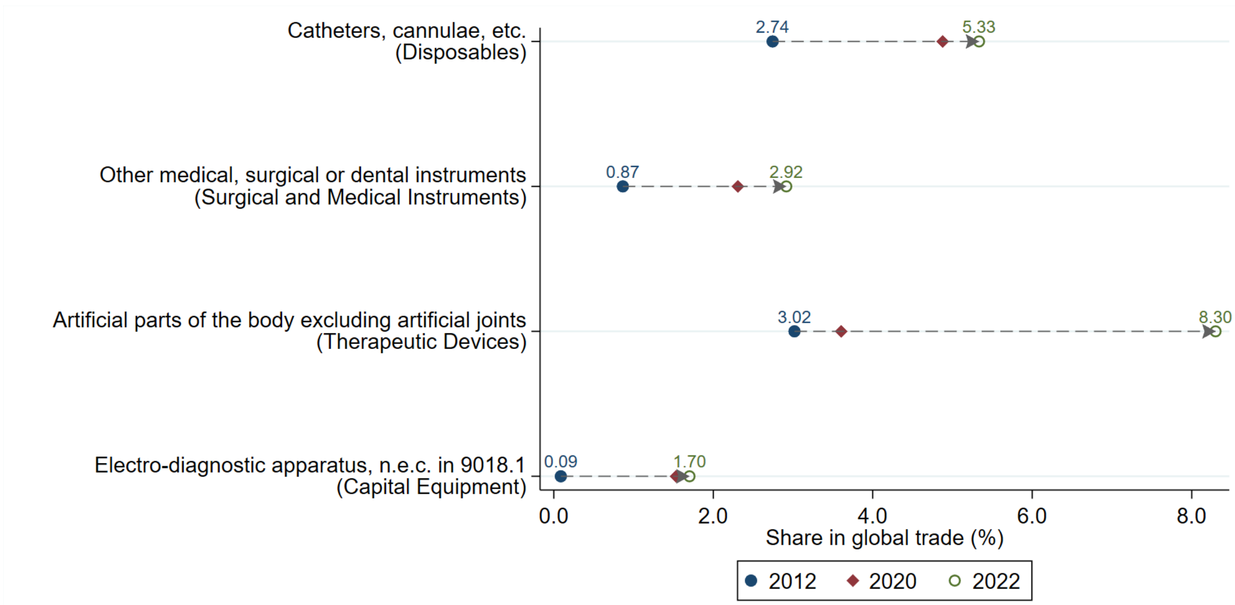
Notes: The flag indicates the country of origin. A star by the side of the firm name indicates that the company is one of the 30 largest medical device firms according to MPO ("The 2023 MPO Top 30 Medical Device Companies Report" available at https://www.mpo-mag.com/heaps/view/11657/?nav=top_nav access on March 15, 2024).

Figure 3. Exports of medical devices' products classified into four groups, Costa Rica, in millions of USD, 2012 and 2022

Panel A. Most exported medical devices

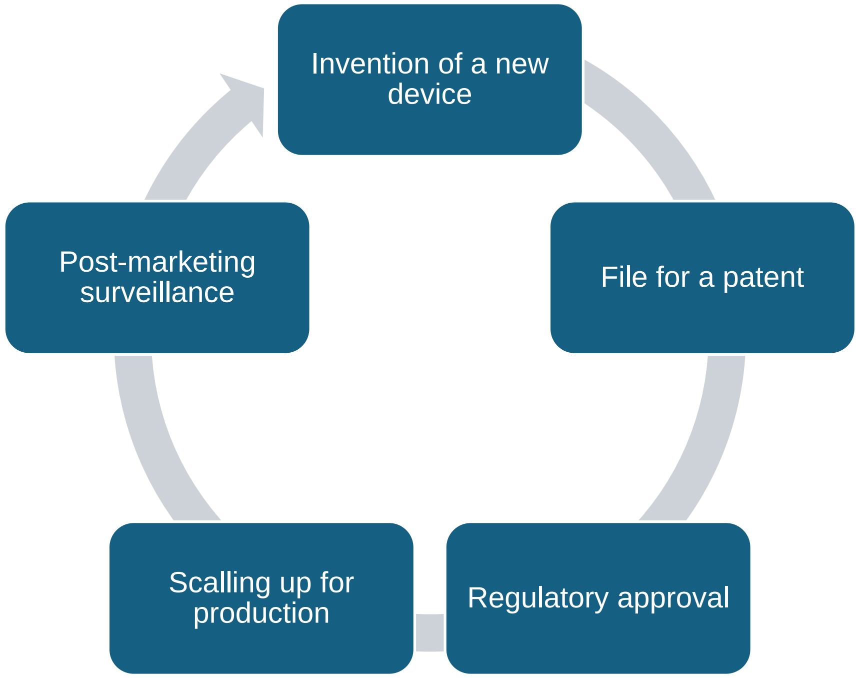


Panel B. Share in global trade of Costa Rican exports



Notes: This figure shows in percentage points the exported value from Costa Rica for each product specified in the vertical axis divided by the value traded globally, in 2012, 2020, and 2022.

Figure 4. The life cycle of a new medical device



Source: Own elaboration based on Gelijns (1989) and WHO (2010).

Appendix A: Additional Tables and Figures

Table A.1 Identification of key informants for interviews

#	Name	Position	Organization
1	Federico Rivera Daniel Calvo Jimena Fletes	President Principal Business Development Partner Executive Director	Medical Device Cluster of Costa Rica
2	Rafael Corrales	CEO	Arenal Medical
3	Fanny Chan Sebastián Ospina Henao	Research and Development Director Coordinator	Research Institute of Medical Sciences (UCIMED)
4	Gabriella Couto	Founder	Costa Rican Cluster for Biotechnology, Medical Devices and Life Sciences (CRBIOMED)
5	Ricardo Monge	President	Central America Academy
6	Ronald Brenes Brenes	Course Director Master's Degree in Medical Device Engineering	Costa Rica Institute of Technology
7	Erick Mora Gloriana Lang	life Science Lead Innovation and Development Lead	Costa Rican Investment Promotion Agency (Cinde)
8	Gabriela Castro	Former director of public policy for Foreign Direct Investment	Ministerio de Comercio Exterior (Comex)
9	Marcial Chaverri	Director of Creation of New Exporters and Access to Financing	Promotora de Comercio Exterior (Procomer)
10	Laura Ramírez Saborío Angélica Cordero Solís	Executive Director Director of Evaluation and Accreditation	Sistema Nacional de Acreditación de la Educación Superior (SINAES)
11	David Ramírez	Innovation and Entrepreneurship Coordinator	Sistema de Banca para el Desarrollo (SBD)
12	Eduardo Loría	Commercial Coordinator	Technical Standards Institute of Costa Rica (INTECO)
13	Marco Antonio Vargas	Chief Commercial Officer	Grupo Vargas
14	Eduardo Viso	Supply Chain Manager	Philips
15	Ivania Alvarado Esteban Campos	Human Resource Manager Supply Chain Director	Edwards Lifesciences

Table A.2 Categories of finished medical devices

Finished products can be classified into four categories. This classification is important for two reasons (Salazar-Xirinais, 2022): i) because each category corresponds to products with increasing value-added degrees, and ii) because these categories are the basis for placing these products in the Standard Industrial Classification (SIC) that guides the collection of trade statistics. These four categories are the following:

1. *Disposables or high-volume commodities* include bandages, surgical gloves, plastic syringes, catheters, and needles. These are “low tech,” generally single-use products that are cost driven. Manufacturing these products requires less medical expertise than other product categories, but producers must comply with specific quality standards.
2. *Surgical and medical instruments* include forceps, medical scissors, dental drills, and specialized surgical instruments used in cosmetic and endoscopic surgery. These are generally multi-use products that are sterilized between uses with different patients. Some devices may be electrically powered. The production of many surgical and medical instruments is increasingly cost-driven.
3. *Therapeutic devices* include implantable and non-implantable devices to help people manage physical illness or disability. For example, hearing aids, pacemakers, and prosthetics are therapeutic devices. These products are directed towards specialists. Due to their prolonged use inside the body, producing implantable devices requires considerable expertise, particularly concerning bio-compatibility, and obtaining regulatory approval for implantable devices is costly. This increases the value of each device considerably.
4. *Capital equipment* includes single-purchase equipment that can be used repeatedly over several years. These products require ongoing account management for accessories, services, and parts. This product category covers patient monitoring, diagnostics, and imaging equipment. It ranges from infusion pumps and blood pressure monitors to significant investments such as MRI equipment or computed tomography. Equipment requiring these large, long-term investments generally requires multiple decision-makers.

Table A.3. Value exported in millions of US dollars in 2012, 2020, and 2022, in Costa Rica and the world, of medical devices, by product category and commodity code.

Product Category (1)	Commodity Code (2)	Commodity Description (3)	Costa Rica 2012 (4)	Costa Rica 2020 (5)	Costa Rica 2022 (6)	Worldwide 2012 (7)	Worldwide 2020 (8)	Worldwide 2022 (9)
Disposables	901831	Syringes	15.9	2.3	0.1	4,275.5	5,695.0	6,613.4
	901832	Needles	0.0	40.0	53.4	1,775.1	2,762.7	3,505.0
	901839	Catheters, cannulae, etc.	604.6	1,498.2	1,996.2	22,028.4	30,721.4	37,430.8
Surgical and Medical Instruments	901841	Dental drill engines	0.0	0.0	0.0	415.7	574.7	616.7
	901849	Dental instruments other than dental drill engines	6.6	0.1	0.2	4,022.0	4,823.4	6,865.1
	901850	Ophthalmic instruments and appliances	0.3	2.7	7.0	3,417.2	3,738.9	5,171.9
	901890	Other medical, surgical or dental instruments	359.5	1,313.1	1,894.3	41,507.1	56,869.5	64,961.6
Therapeutic Devices	900130	Contact Lenses	0.1	87.5	62.5	4,922.7	6,354.0	7,205.2
	902110	Orthopedic appliances	1.6	32.5	85.1	7,382.4	9,398.6	11,076.5
	902121	Artificial teeth	0.0	6.0	6.0	616.8	808.2	1,095.3
	902129	Dental fittings other than artificial teeth	0.1	0.0	0.1	1,990.3	2,872.9	4,021.4
	902131	Artificial parts of the body	0.1	1.8	0.1	5,745.5	10,153.6	12,623.2
	902139	Artificial parts of the body excluding artificial joints	233.3	382.2	1,052.3	7,729.6	10,600.7	12,679.8
	902140	Hearing aids	0.1	0.0	0.0	3,128.3	3,941.5	5,239.3
	902150	Pacemakers for stimulating heart muscles	0.0	0.0	0.0	6,025.2	4,342.3	6,130.1
	902190	Disability Appliances	36.1	179.4	43.6	11,770.4	12,564.3	15,807.8
Capital Equipment	901811	Electro-cardiographs	0.0	0.5	4.9	780.9	1,061.4	1,209.2
	901812	Ultrasonic scanning apparatus	0.1	0.1	62.9	4,388.6	4,815.4	5,614.8
	901813	Magnetic resonance imaging apparatus	0.0	0.0	0.0	4,509.8	4,450.9	5,296.2
	901814	Scintigraphic apparatus	0.0	0.0	0.0	328.0	309.6	328.2
	901819	Electro-diagnostic apparatus, n.e.c. in 9018.1	8.7	235.3	285.7	9,768.9	15,345.6	16,787.7
	901820	Ultra-violet or infra-red apparatus	0.0	0.0	0.1	356.8	654.3	690.3
	902212	Computed tomography apparatus	0.0	0.4	1.5	3,077.5	4,240.8	4,970.5

902213	X-rays for dental uses	0.0	0.0	0.0	795.5	670.7	856.6
902214	X-rays for medical, surgical or veterinary uses	0.0	0.0	0.0	5,891.0	5,766.0	5,947.5
902219	X-rays for other uses	0.0	0.1	0.0	2,434.6	2,565.7	2,994.1
902221	Radiography or radiotherapy apparatus for medical uses*	0.0	0.0	0.0	509.2	324.8	304.7
902229	Radiography or radiotherapy apparatus for other uses	0.0	0.0	0.0	286.0	169.0	328.0
902230	X-ray tubes	0.2	0.1	0.0	1,813.7	1,740.7	2,047.6
902290	X-rays parts and accessories	0.3	0.7	3.1	7,589.4	6,921.2	7,498.2
	TOTAL	1,267.6	3,783.0	5,559.1	169,282.1	215,257.8	255,916.7

Source: own elaboration using data from Comtrade. The list of commodity codes includes all six-digit codes under the four-digit codes 9018, 9021, and 9022, plus 900130 (contact lenses).

Table A.4: Free Trade Zone exemptions and regular tax rate in Costa Rica for a medical device firm looking to establish in the city of San José and surrounding areas.

Taxes in Costa Rica / others	Tax rate	Free Trade Zone Regime
Income tax	30%	6% years 1 to 8, 15% years 9 to 12, 30% after year 12
Import/export tariffs	Varies depending on the product	100% exemption
General sales tax	13%	100% exemption on local purchases of goods/services
Stamps	1%	100% exemption
Municipal license	0.3%	100% exemption for a period of 10 years
Tax on the transfer of real estate	1.5%	100% exemption for a period of 10 years
Tax on withholding of royalties, fees, and dividends	up to 25%	100% exemption
Interest tax	8%	100% exemption
Limitation of expatriates in the country	None	
Expatriate tax	All residents and non-residents working within Costa Rica's territory under an employment relationship are subject to withholdings and social security contributions. The personal income tax is increased to 15%.	
Entry requirements	Minimum investment of 150,000 USD and maintain a certain level of employment set by the company.	

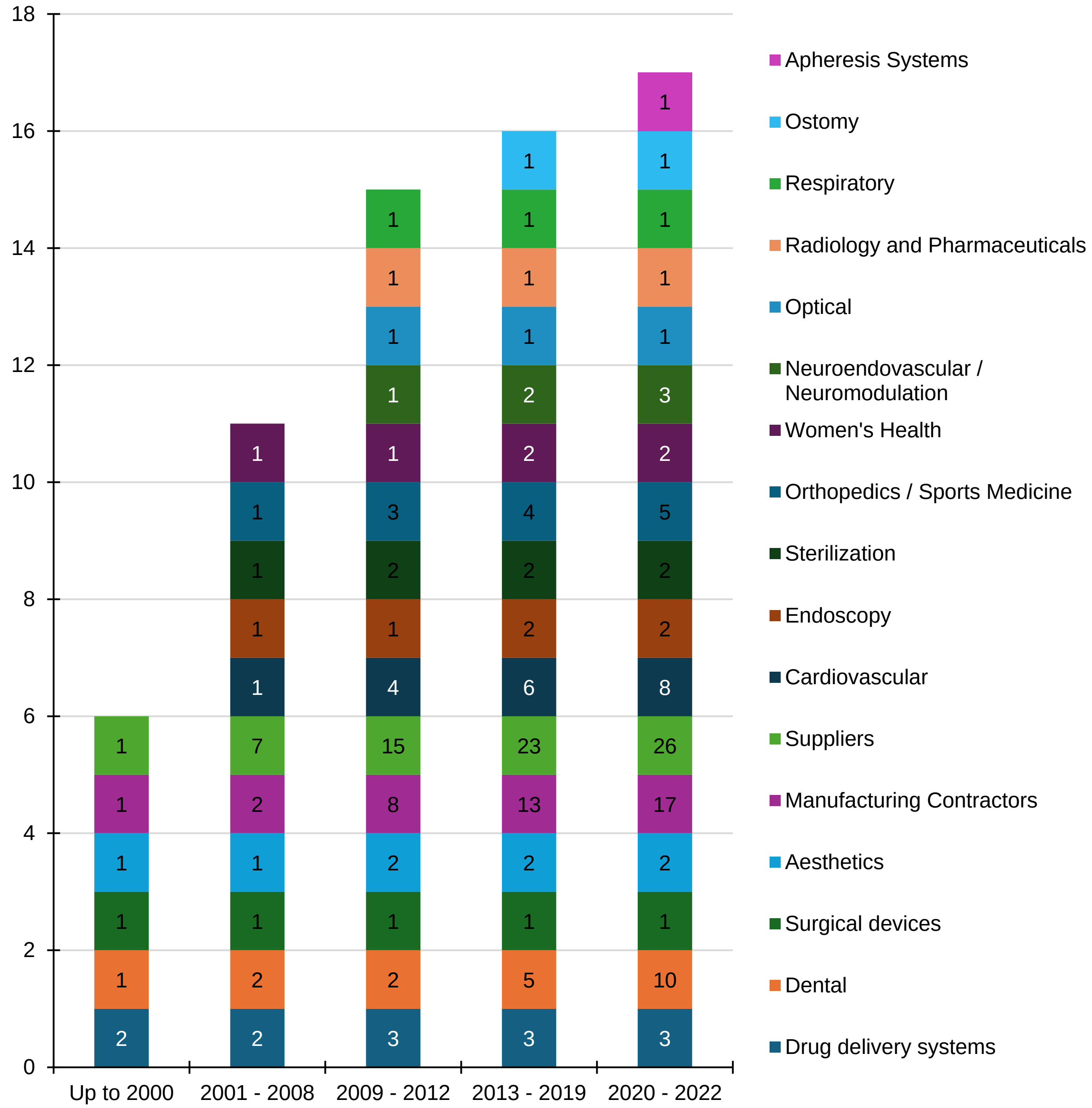
Notes: GAM stands for Great Metropolitan Area. Additional benefits and requirements may apply for other manufacturing firms, for firms looking to establish outside GAM, or for manufacturing firms whose initial investment is over 10 million USD (known as "Megaprojects"). Source: Cinde and Procomer (available at https://www.procomer.com/wp-content/uploads/Guia-Zonas-Francas-Ing-dic-2021.pdf accessed March 15, 2024).

Table A.5. Employee Profile for Select Segments of the Value Chain

Value Chain Stage	Professional Labor with Tertiary Education	Technicians and Operators
R&D	Clinicians (incremental & radical innovation) Engineers (incremental innovation) (mechanical, Electronic, biomedical, electrical, chemical, industrial, process) Product designers PhDs with industry experience and capacity in applied research Government & regulatory affairs officers Risk capital specialists (angel investors, venture capitalists)	Highly skilled technicians (prototypes)
Components	Engineers (chemical, electrical, electronic, industrial, mechanical, automation) Validation engineers Quality assurance Microbiologists	Mechanics Electricians Technicians Machine operators Manual assemblers
Assembly	Engineers (chemical, electrical, electronic, industrial, mechanical, automation) Validation engineers Quality assurance Microbiologists Compliance officers (lawyers, documentation clerks)	Mechanics Electricians Technicians Machine operators Manual assemblers
Marketing & Sales	Government & regulatory affairs officers Health economics specialists Reimbursement specialists Marketers Product specialists	

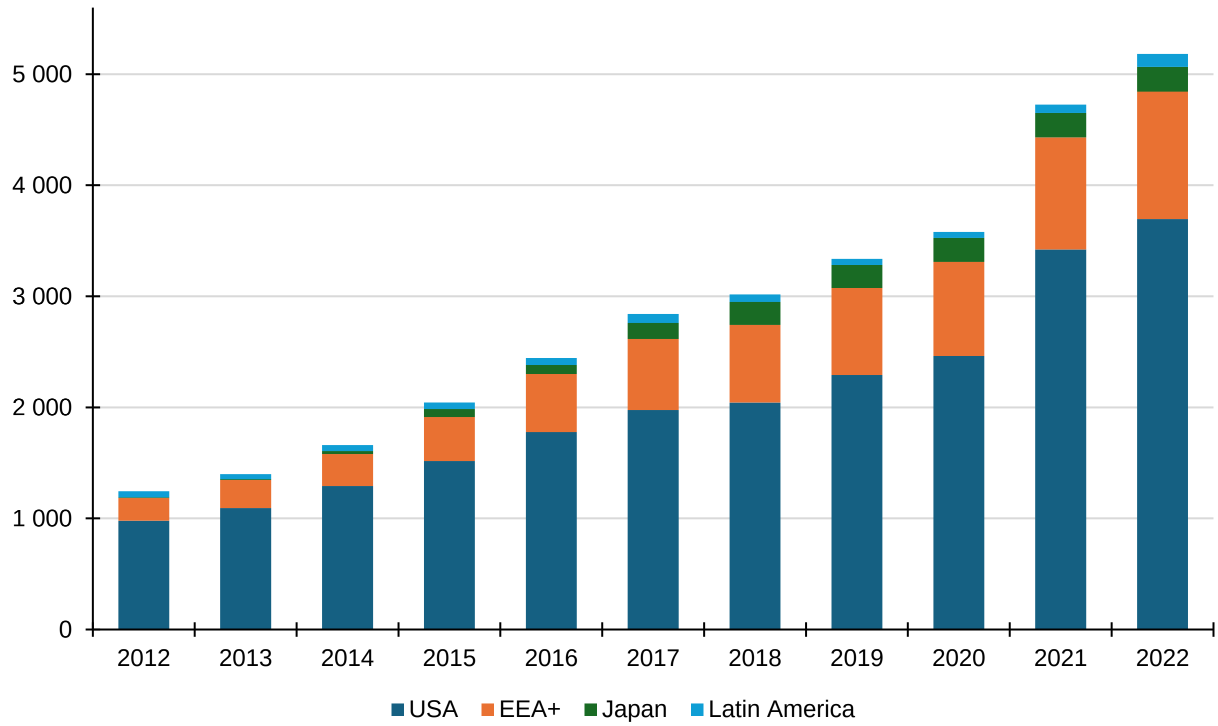
Source: Bamber and Gereffi (2013)

Figure A.1. Market segments of the medical devices sector with presence in Costa Rica, since 1987, and number of firms by segment.



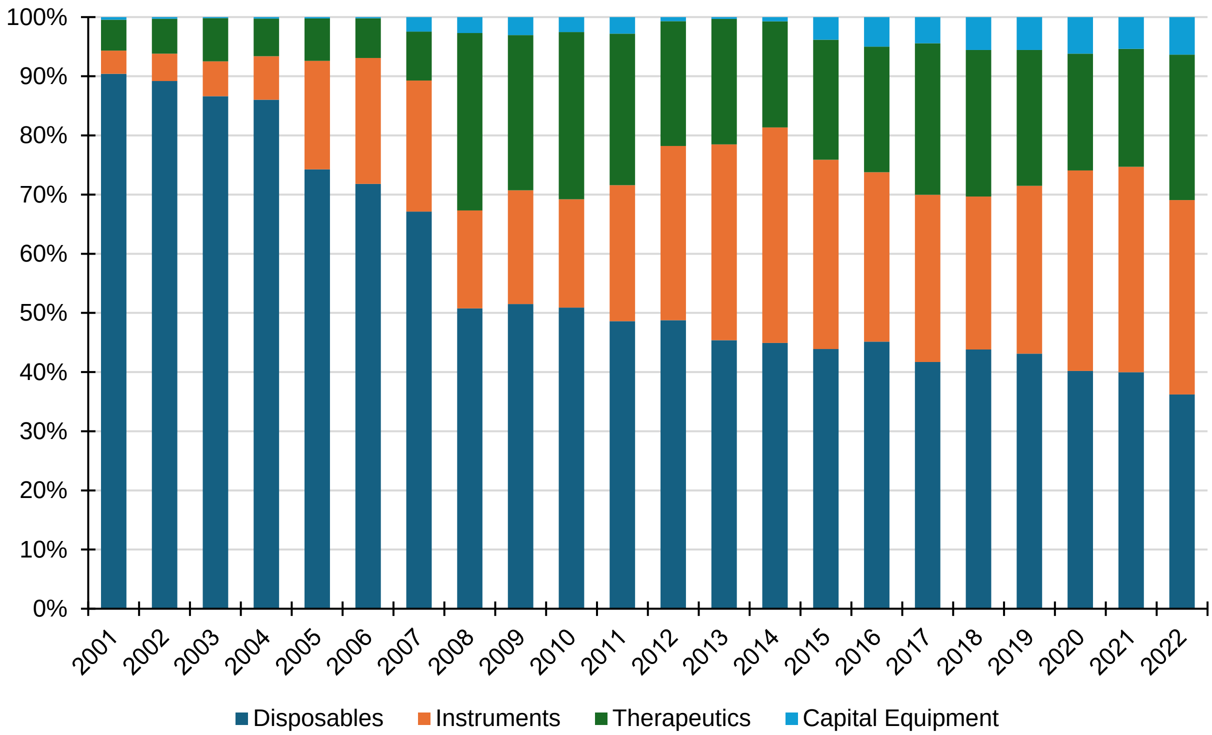
Notes: the number inside each bar is the number of firms in each market segment. Source: own elaboration using data from Cinde.

Figure A.2. Medical Devices, Costa Rican exports by destination, 2012 to 2022, millions of USD



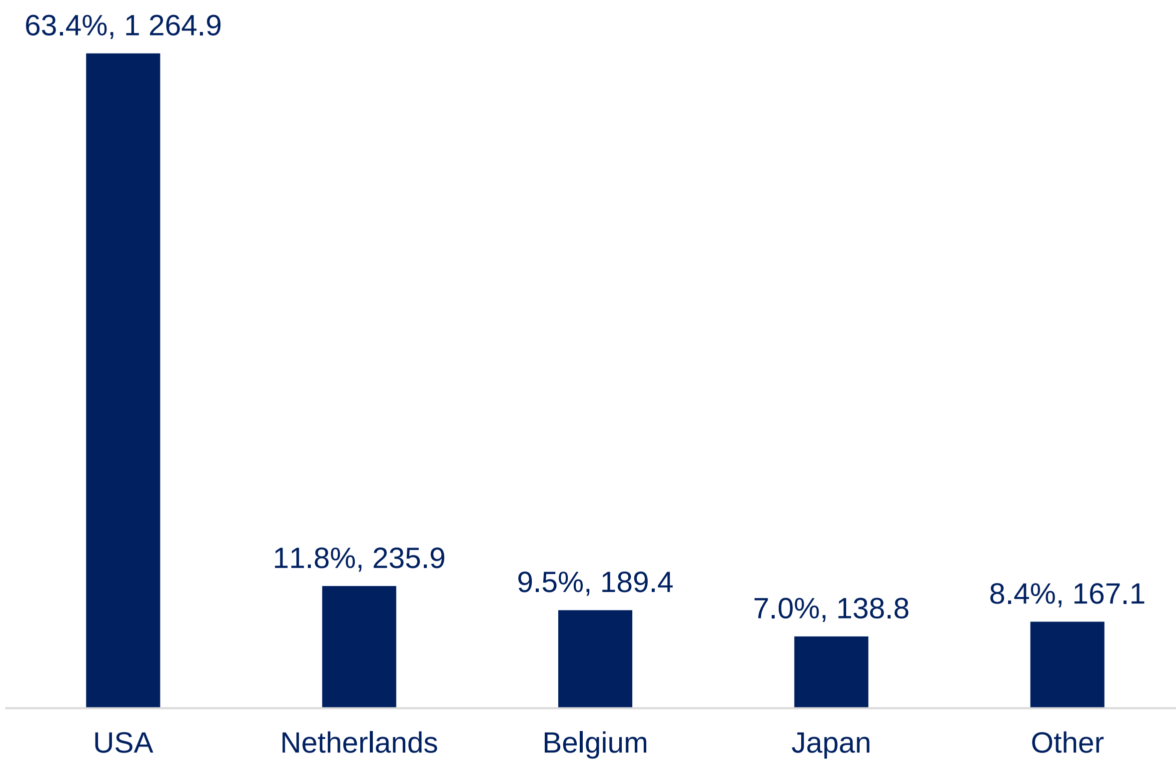
Notes: EEA+ is the European Economic Area that includes the 27 countries from the European Union plus Iceland, Liechtenstein, Norway, and Switzerland. Source: own elaboration using Comtrade data.

Figure A.3. Medical Devices, Costa Rican exports by product category, 2001–2022



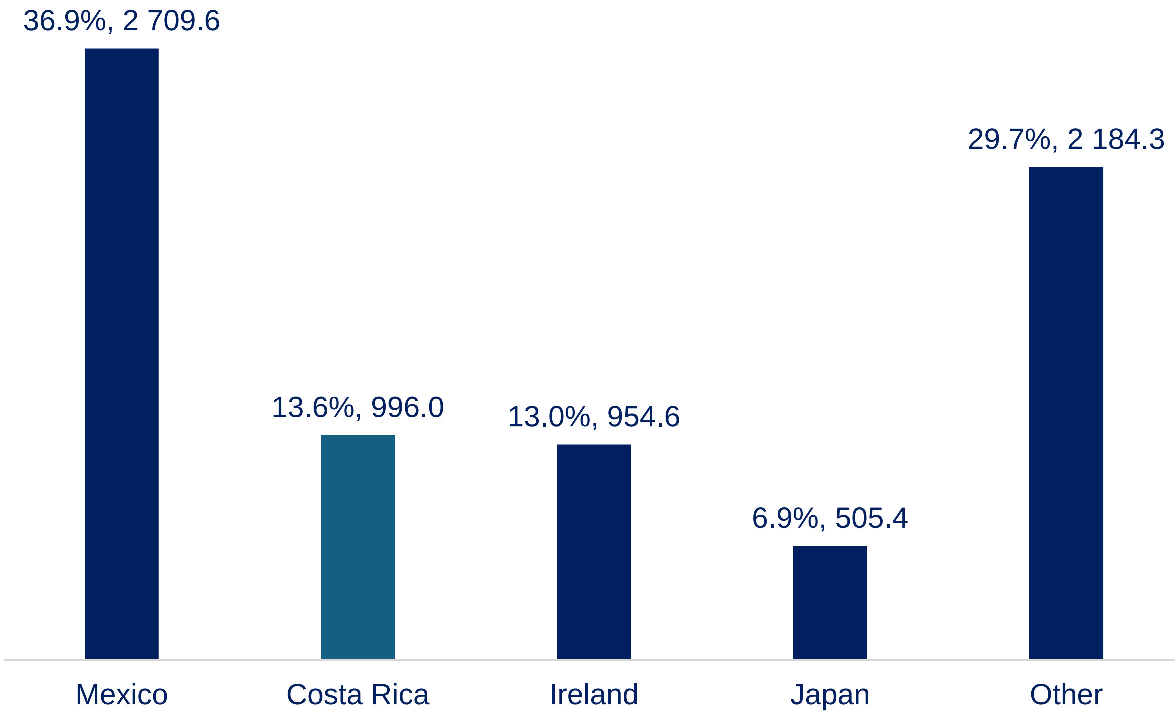
Source: own elaboration using data from Cinde and Bamber and Gereffi (2013) classification.

Figure A.4 Exports of catheters from Costa Rica by destination (MM US$, 2022)



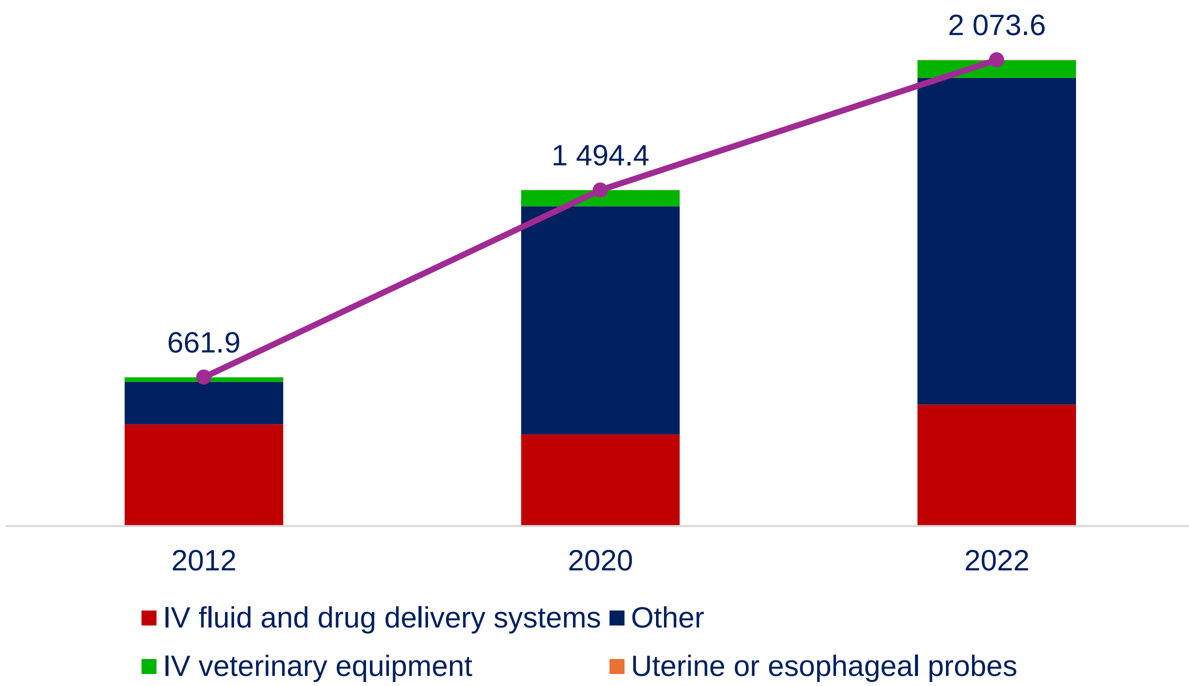
Source: own elaboration.

Figure A.5 US imports of catheters by partner (MM US$, 2022)



Source: own elaboration using data from Comtrade.

Figure A.6 Exports of catheters (901839) by type (2012-2022)



Source: own elaboration using data from Procomer.

Figure A.7 Exports of 902139 from Costa Rica by destination (MM US$, 2022)

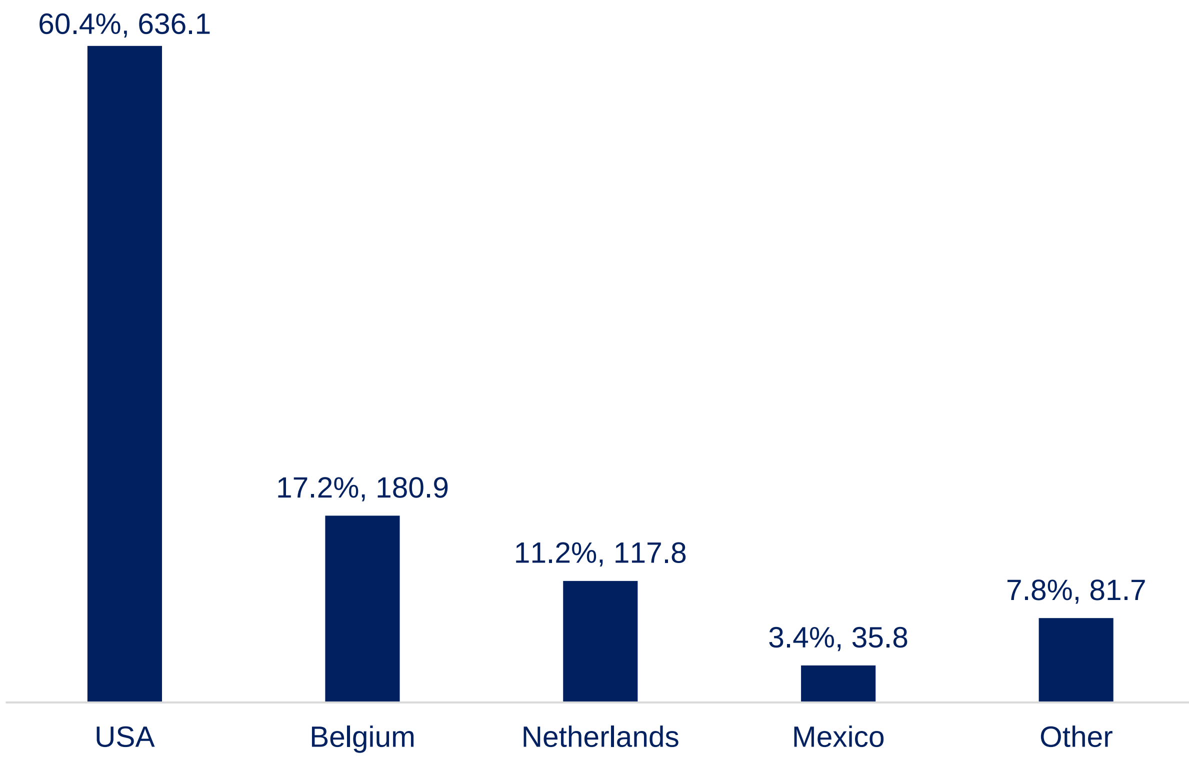


Figure A.8 US imports of 902139 by partner (MM US$, 2022)

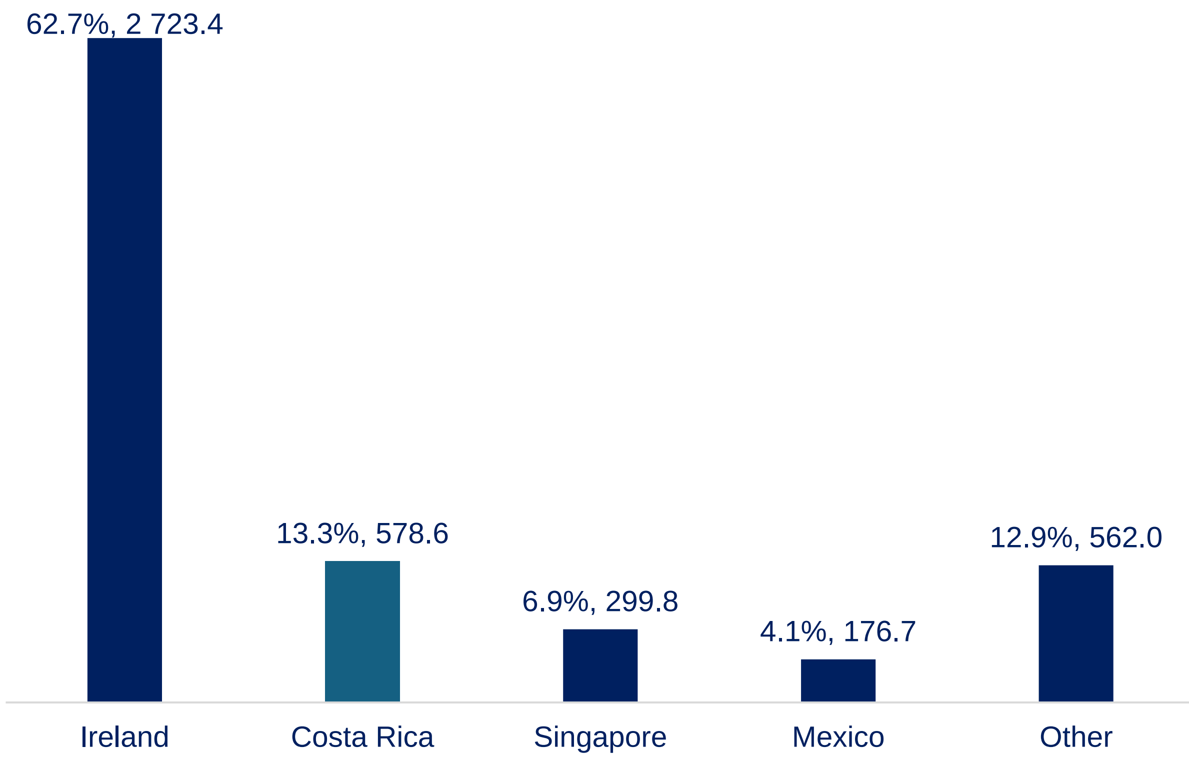
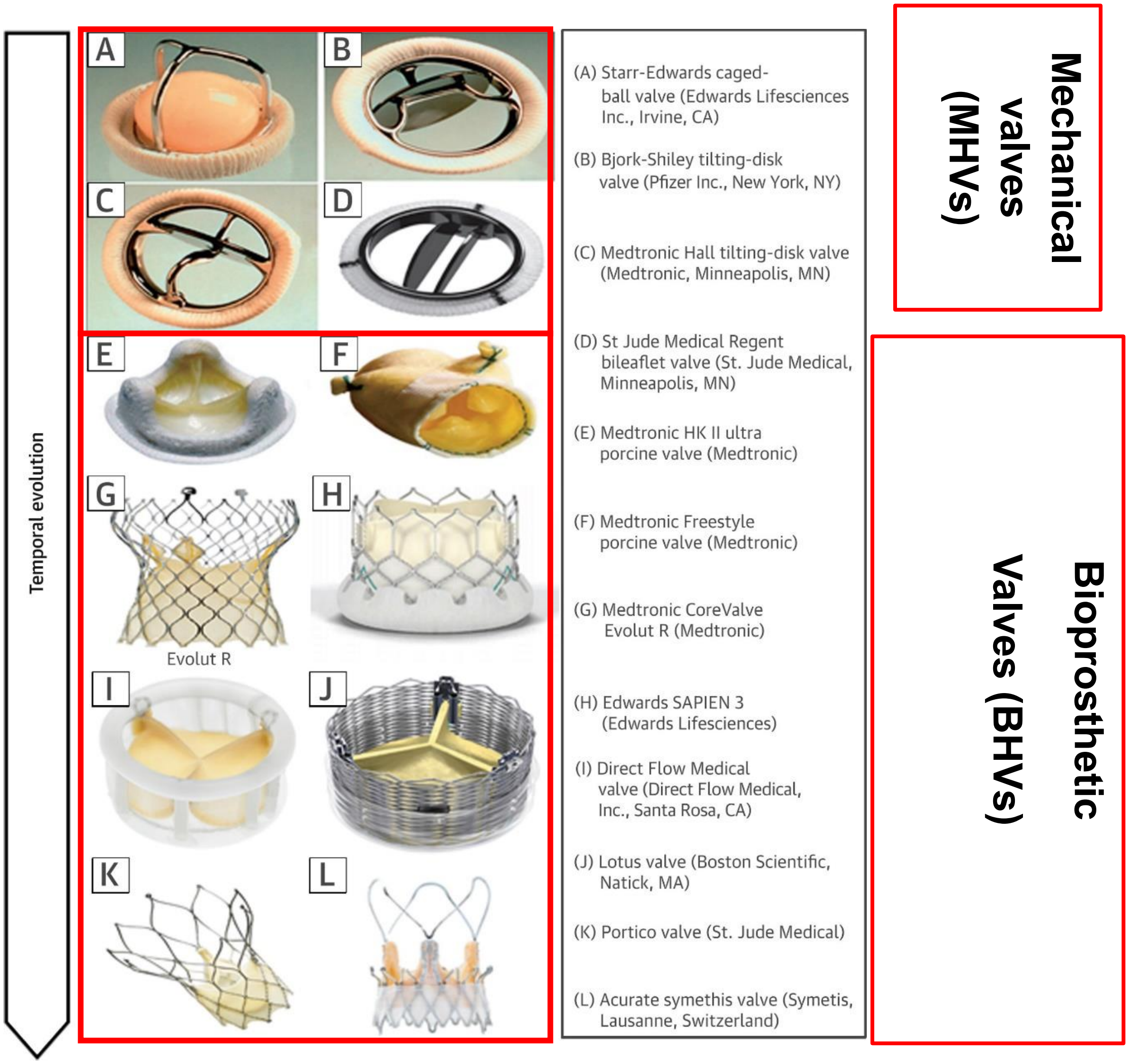


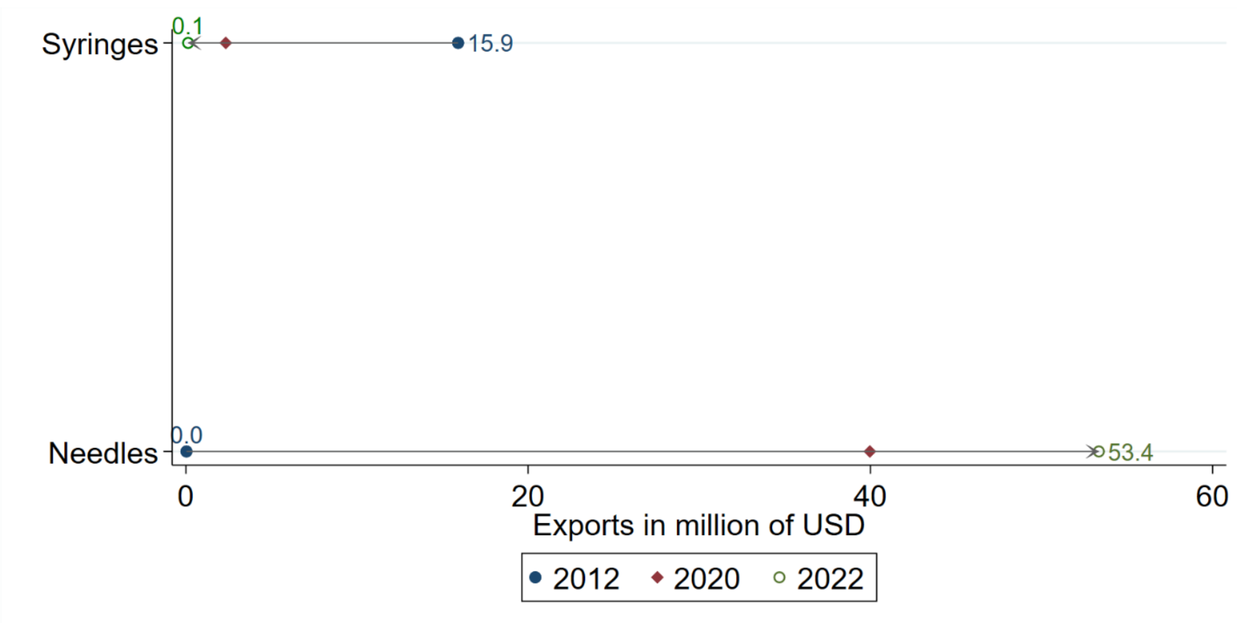
Figure A.9 Surgical and Transcatheter Prosthetic Heart Valve Examples. Evolution of surgical and transcatheter prosthetic heart valves.



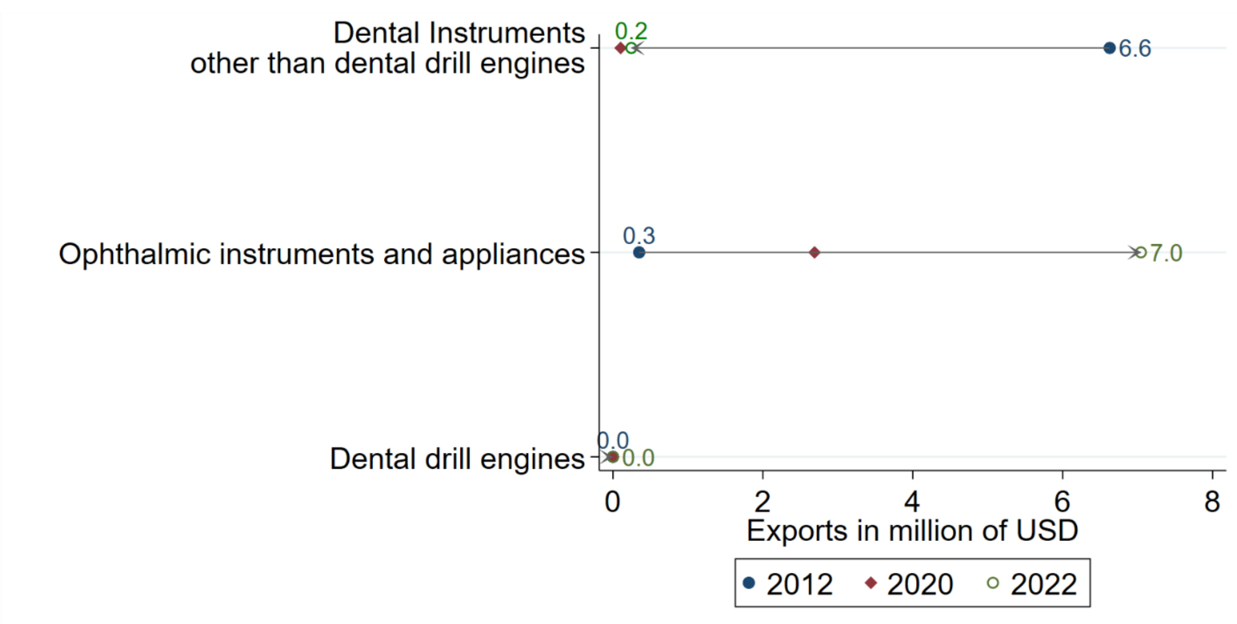
Source: Figure 1 from Dangas et al. (2016).

Figure A.10 Exports of medical devices' products by category and product, Costa Rica, in millions of USD, 2012, 2020, and 2022

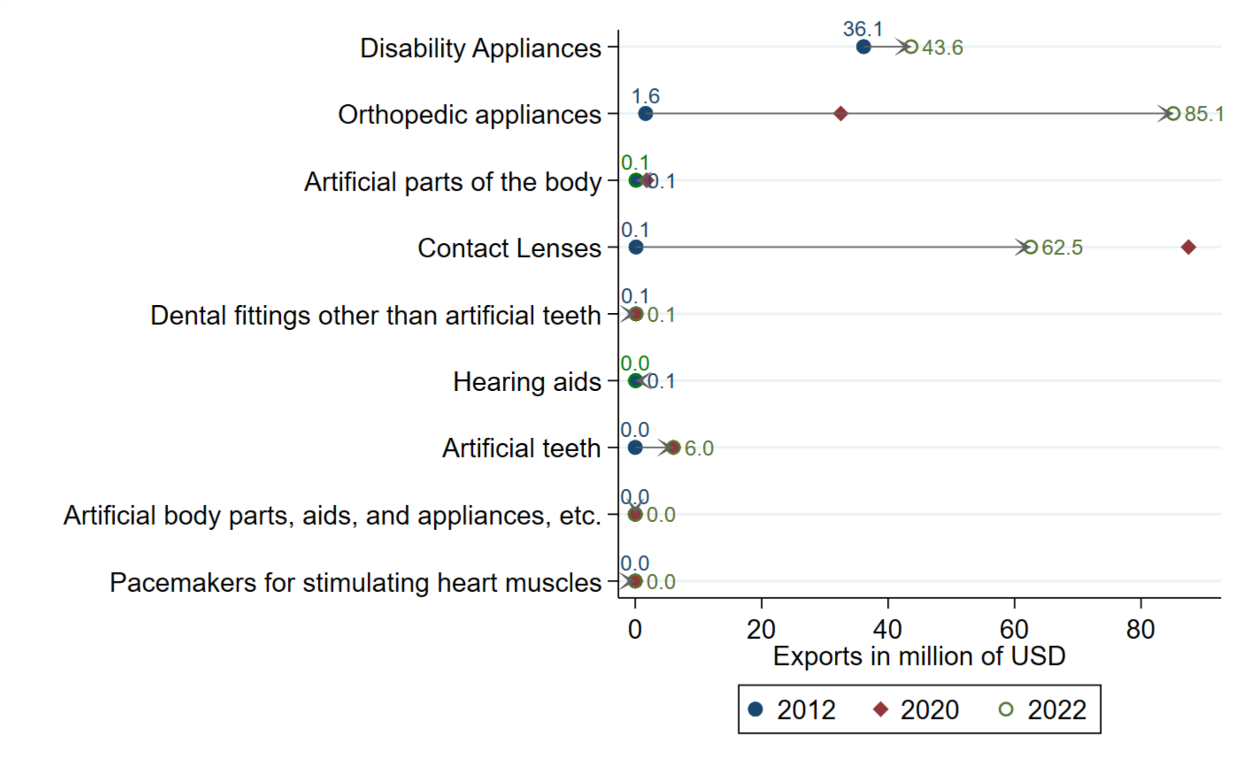
Panel A. Disposables



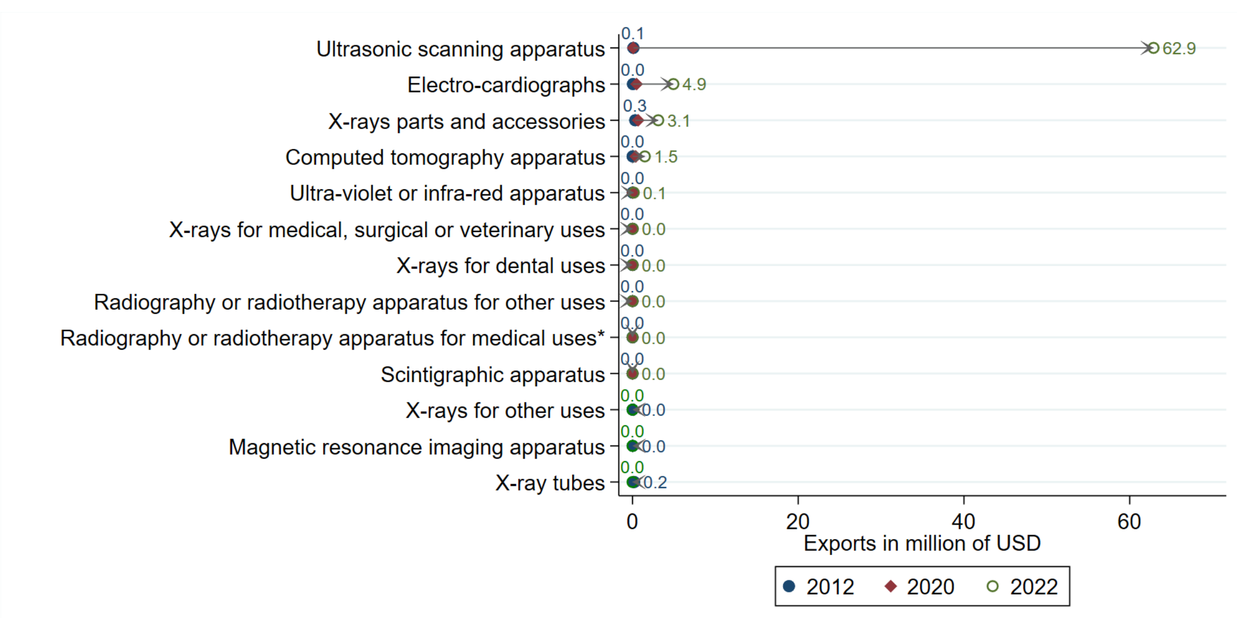
Panel B. Surgical and Medical Instruments



Panel C. Therapeutic Devices

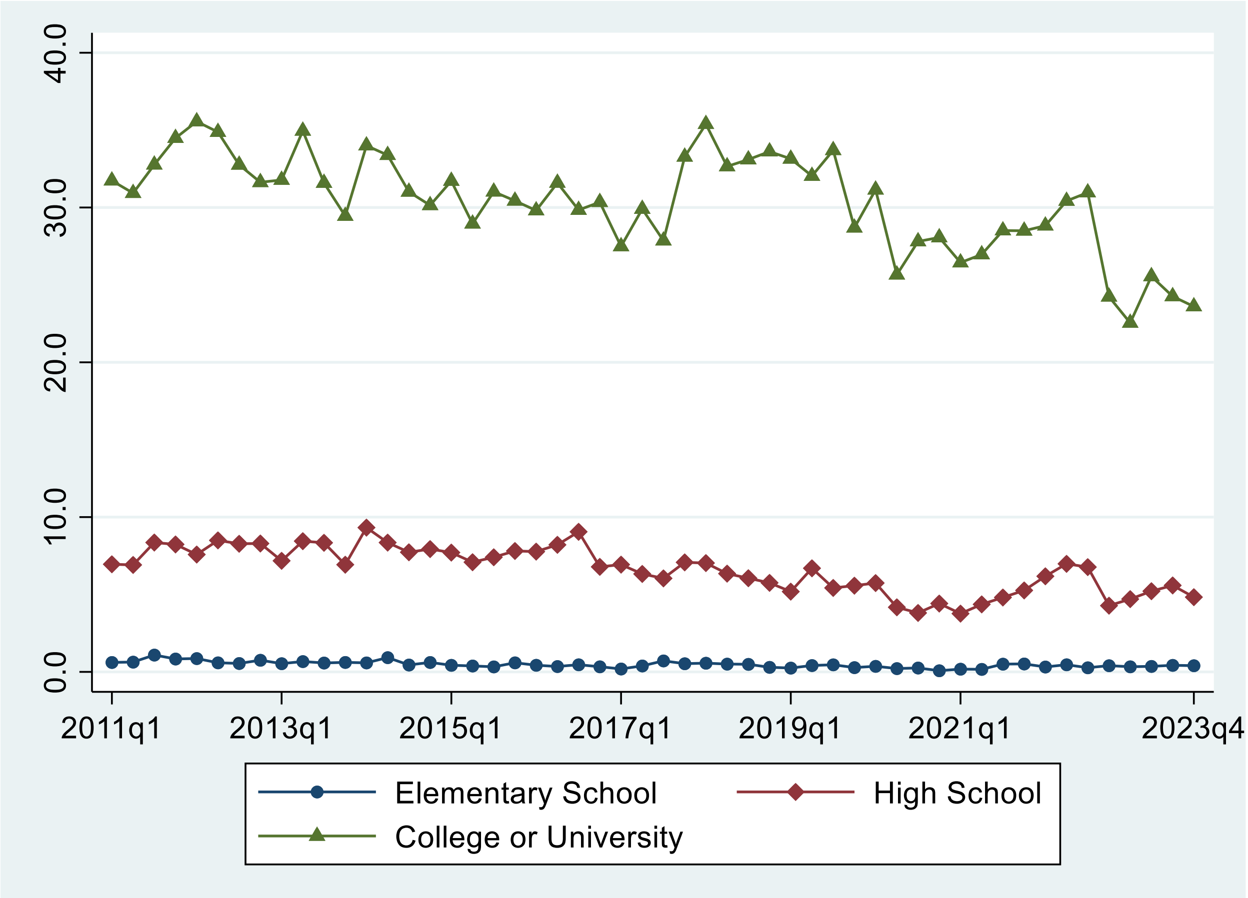


Panel D. Capital Equipment



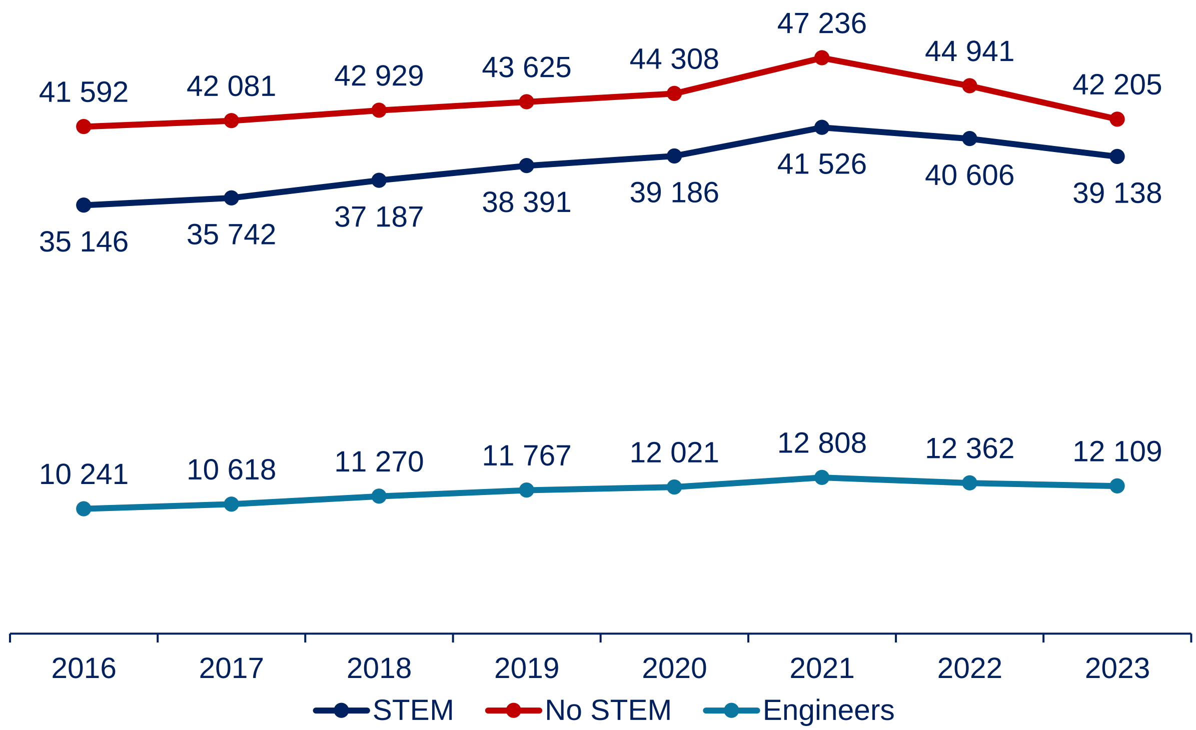
Source: own elaboration using data from Comtrade.

Figure A.11 Percentage of people who speak and write English, by academic degree, from the first quarter of 2011 to the last quarter of 2023.



Source: Own analysis using as a data source all the available quarterly rounds of the *Encuesta Continua de Empleo* (ECE) labor survey of Costa Rica carried by the local institute of statistics (INEC).

Figure A.12 Number of freshmen in public universities in Costa Rica



Source: own elaboration from analysis of CONARE data.

Appendix B: Interview Question Guide for the Sector.

The question guide serves as a conversation guide during the interviews. The questions were formulated based on an initial review of literature about the sector in Costa Rica (Bamber & Gereffi, 2013; Gibson, 2022; Pietrobelli et.al., forthcoming; Santos & Durán, 2023, Salazar-Xirinachs, 2022; Valverde, 2023) and the evolution of global value chains (Pietrobelli, 2021; Pietrobelli et.al. 2021). The intention is to follow a process of semi-structured interviews, allowing exploration of topics raised by the interviewee as relevant to the interview continuation. The guide presents a comprehensive list of topics to be addressed during the data collection process. Prior to the interview, the research team will select the most relevant questions based on the interviewee's expertise and the relevance to specific themes.

1. Can you tell us about the role of your organization in the ecosystem of the Medical Devices and Life Sciences sector in Costa Rica?

2. From your perspective, how has the D31T33 sector evolved in Costa Rica over the last two decades?

3. What does the value chain in the medical devices sector include? a. What has Costa Rica successfully included in its production? b. What needs to be included to increase the generated value?

4. What are the determining factors that have contributed to the sector's growth in the country during the last two decades of sector development?

5. Are there identifiable obstacles that have hindered sector development during this period? a. For example, in an ideal scenario, what prevented them from growing twice as much in the sector? b. Are there missed opportunities in the sector's development over the last two decades, and what could have resulted in more positive outcomes?

6. How do you compare operating costs in CR vs. other countries in the region and the world in this sector? a. Has the sector recently benefited or been affected by the dynamics of nearshoring with significant markets like the USA? b. Has the sector recently benefited or been affected by the dynamics of friendshoring?

7. How has verticalization and integration forward and backward in the production chain been managed? a. How has market diversification and entry into higher-value segments of the medical devices sector evolved in Costa Rica?

8. How have specific challenges related to regulation and uncertainty in Costa Rica affected attracting investments and expanding the medical devices sector? a. How has technical regulation impacted the sector's process of attracting foreign direct investment? b. Are bureaucratic processes a factor in attracting FDI? And in the development and growth of sector companies? c. How has the investment attraction policy influenced identifying and filling gaps in the value chain?

9. How has coordination and collaboration between multinational companies and local suppliers impacted the sector's growth? a. Were there public-private coordination efforts that allowed the development of coordination and collaboration between multinational companies and local suppliers? b. What challenges have been identified for collaboration between these two industry actors? c. How has local chaining and the participation of local suppliers in the D31T33 sector developed? d. How has the existence of clusters contributed to knowledge exchange and sector competitiveness in the country? e. What has been the role of technology transfer in the growth and development of the medical devices industry in Costa Rica? f. Are there significant obstacles in technology transfer, and how have they been addressed? g. How has access to contact information for industry suppliers in Costa Rica been? h. What are the barriers to the effective participation of local suppliers, and how could they be overcome?

10. How do companies in the D31T33 sector in Costa Rica perceive the availability of postgraduate human resources in key disciplines such as information and communication technologies (ICT), highly specialized engineering, industrial design, electronics, mechatronics, and how has this affected their ability to move towards higher value-added segments? a. How have academic curriculum contents related to the medical devices industry evolved? b. How has the quality of engineering and business graduates evolved in relation to sector needs? c. What identified obstacles exist for implementing changes in study plans, and how could they be overcome?

11. What are the experiences of companies regarding the links between them and academia in the D31T33 sector in Costa Rica? a. In terms of public sector support, how do companies evaluate collaboration with the government and academia in research and development initiatives? b. How have these links affected companies' ability to overcome obstacles and seize opportunities? c. Are there suggestions to strengthen this collaboration and improve government support for the sector? d. How could links between government, academia, and industry be improved to drive innovation in the D31T33 sector in Costa Rica, from the perspective of companies?

12. In terms of procedures and regulations, how do companies experience difficulties, including importing inputs for research and development (R&D)? a. How has this affected the agility and competitiveness of the sector? b. What solutions do they propose to improve these processes?

13. How has the national quality system affected the development of clinical trials and laboratory accreditation in Costa Rica? a. Are there specific barriers to the implementation of quality standards, and how have they influenced the growth of the medical devices and life sciences sector? b. How have international quality standards influenced export strategies and access to international markets? c. Are there specific challenges in adapting to these standards, and how have sector companies addressed them?

14. What are the impacts of the shortage of specialized laboratories with quality certifications on the development of new technologies in the D31T33 sector in Costa Rica? a. How have

companies faced this limitation, and which opportunities have been affected? b. How does this affect the capacity for innovation and the development of new technologies in the D31T33 sector in Costa Rica? c. How has laboratory accreditation and the National Quality System influenced the development of clinical trials in the sector?

15. What is companies' perception of the costs involved in research and development in the medical devices sector in Costa Rica? a. How do these costs affect or benefit companies' ability to move towards higher value-added segments?

16. What has been the experience of companies regarding access to capital for the development of research and development projects in the medical devices sector in Costa Rica? a. What is the industry's perception regarding incentives for innovation and risk-taking in research development? b. What are the main challenges in this aspect, and what suggestions do they have to improve access to financing? c. Are there specific policies that could encourage greater innovation in the sector?

17. How has access to capital (seed capital and venture capital) been for the creation of new companies and for local companies (Small and Medium Enterprises) in the medical devices sector in Costa Rica? a. What challenges have they faced in this regard, and what measures do they propose to improve access to financing?

18. Considering the lessons learned from previous experiences, what are the best practices that could be shared to address identified challenges and maximize opportunities in the medical devices sector in Costa Rica? a. What lessons can be drawn from Costa Rica's experience in identifying and addressing "critical gaps" in technical capabilities to attract foreign investment?

19. Considering the current sector situation, what are the critical gaps that must be addressed to increase opportunities in the medical devices sector in Costa Rica? a. What challenges and areas of improvement have been identified to facilitate the sector's future growth in the country? b. What are the specific challenges and opportunities for specialization in highly complex medical products? c. What situations need to be addressed promptly to increase the added value of Costa Rica's production in the global sector chain? d. What situations need to be addressed in the medium and long term?