



China's Changing Medical Device Exports

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Abstract

During the early years of the period 2001–16, the majority of China's medical device exports were low-technology goods. However, the composition of these exports has gradually shifted towards medium-and-high-tech devices. Since 2012, these goods have become China's leading medical device export categories. This article discusses two factors behind this trend: (1) the country's large and growing healthcare market, which has created opportunities for local producers to supply all segments within the sector, and (2) government policies that have prioritized the production of innovative medical devices from local companies.

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Introduction

During the first part of this century, China's medical device exports were largely composed of low-technology goods. Their leading exports during this time were disposable hospital supplies, such as bandages, first-aid kits, and surgical gloves, which represented between 20 and 40 percent of China's medical devices exports during 2001–16. However, China's medical device production steadily penetrated higher-value-added segments of the global marketplace; by 2012, the bulk of China's exports were medium- to higher-tech medical devices, including therapeutic devices and diagnostic equipment.

This dramatic shift in the composition of China's medical device exports was largely driven by China's increasingly robust healthcare market, which is creating opportunities for local producers—whose prices can be considerably lower than that of multinational enterprises (MNEs)—to supply all segments within the sector. Increased domestic market share has translated into opportunities for these firms to fulfill demand in foreign countries, where price sensitivity is paramount. Another substantial driver has been Chinese government policies aimed at cultivating innovative capacity among domestic companies.

Medical Device Production Segments

The medical device industry makes diverse products, ranging from simple, low-tech goods, like bandages, to complex, high-tech capital equipment. There are four major product groupings:²

- 1) *Disposables*, which are the least complex products in the medical device industry, consist of mostly hospital supplies, such as bandages, surgical gloves, plastic syringes, and first-aid kits. These products are subject to fewer regulatory requirements than the others due to the relative simplicity of their construction and the limited potential harm caused to the patient.
- 2) *Surgical and medical instruments* are medical devices used in various procedures ranging from cosmetic and endoscopic procedures to open-heart surgeries and organ transplants; examples include forceps, scissors, and dental drills. These devices often require sterilization due to their frequent use on multiple patients.
- 3) *Therapeutics* are a broad category of devices that assist patients with various maladies. Some can be implanted directly into the body; examples are hearing aids, prosthetics, and pacemakers (devices that regulate irregular heartbeats). Others, such as ventilators and infusion pumps, are non-implantable.
- 4) *Diagnostic* equipment helps in the diagnosis of various conditions, such as fractured limbs and cancer. These devices include capital equipment such as computed tomography (CT)

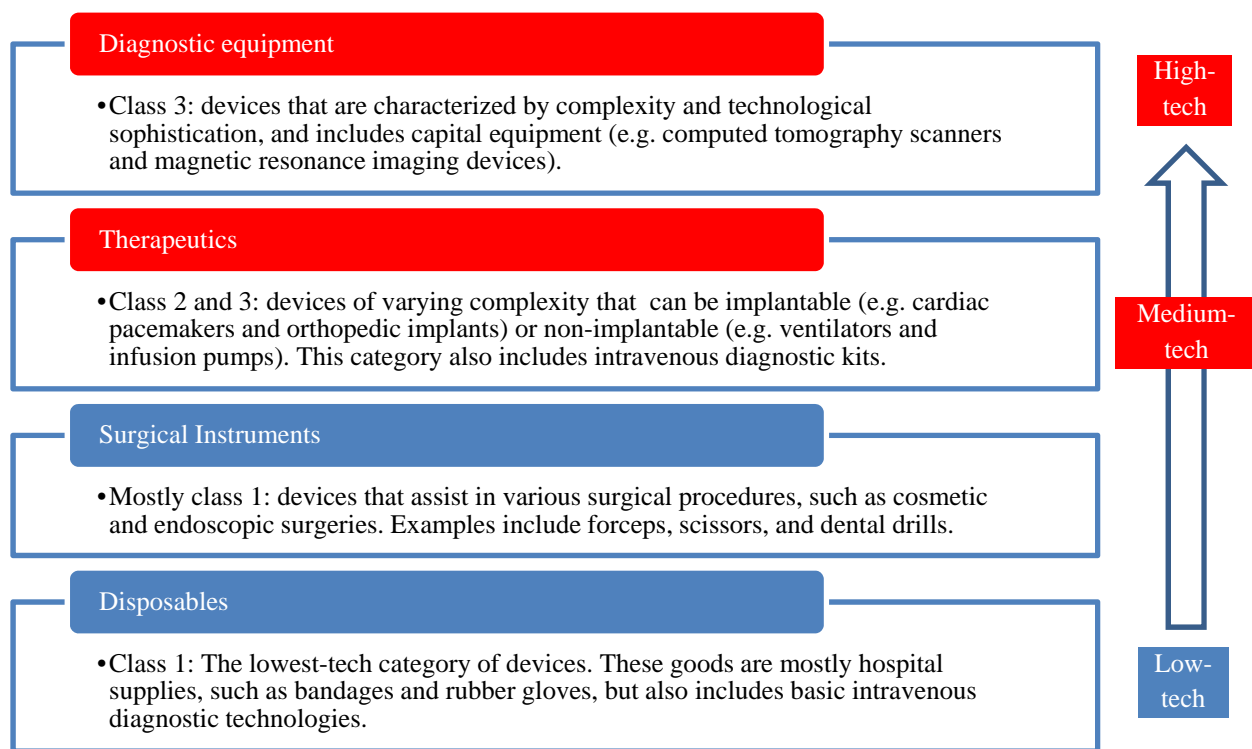
² These categorizations draw exclusively from the definitions provided from the Duke Center on Globalization, Governance and Competitiveness. Bamber and Gereffi, *Costa Rica*, August 2013.

scanners and magnetic resonance imaging (MRI) devices, which can cost hundreds of thousands of dollars. This category includes the most technologically sophisticated medical devices.³

Devices are commonly regulated according to a risk-based classification system; the stringency of a standard reflects its relative complexity and the potential harm posed to consumers. The world's leading medical device markets, such as the United States, Japan, the European Union, and China, all use a similar classification system to regulate medical devices, though the regulatory requirements vary across each of these markets.⁴

In the United States, medical devices are classified in one of three ways: class 1 devices present the fewest health risks to patients and face the lowest approval barriers; class 2 devices pose a slightly greater health risk and are generally seen as similar to an existing product on the market. Class 3 devices are subject to the most rigorous regulatory procedures, such as clinical trials, which can require one to five years before a device is approved for sale.⁵ This classification system can be used as a rough guide to the relative technological sophistication of each of the four main categories of medical devices (figure 1).

Figure 1: Medical device categories and their relative technological complexity



Source: Compiled by author from Bamber and Gereffi, *Costa Rica in the Medical Devices Global Value Chain*, August 2013.

³ For a detailed definition of the various codes in the Harmonized Tariff Schedule of the United States (HTS) assigned to each of these four categories, please refer to appendix A.

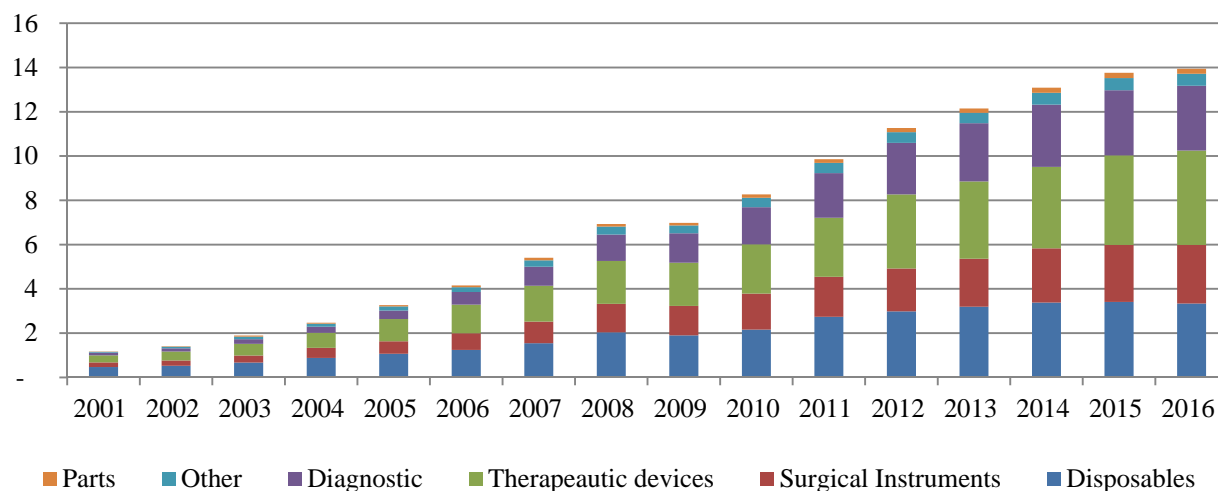
⁴ The different regulatory regimes are reflected in the disparate time to market for devices in these markets. The European Union has the shortest approval time—on average—across all categories of devices among the leading markets. Torsekar, “U.S. Medical Devices,” June 2014.

⁵ Snyder, *Health Care Equipment and Supplies*, May 2017.

China's Shift to High-Tech Medical Device Exports

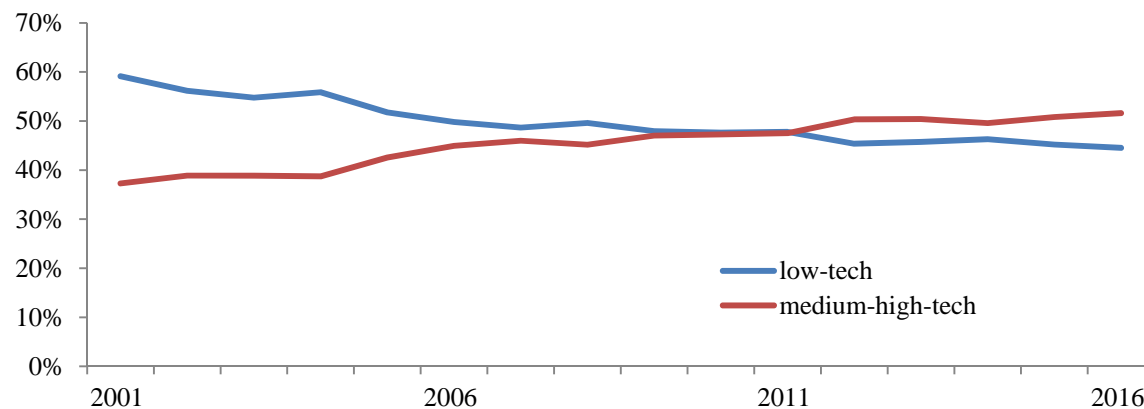
For most of the past two decades, China's medical device exports were characterized by low-tech medical goods. During 2001–11, for example, disposables were China's largest category of medical device exports (figure 2). However, during 2012–16 the composition of China's medical device exports shifted to predominantly medium- to high-tech devices (figure 3). Much of this transition was driven by therapeutic devices and diagnostic equipment. Therapeutic devices have been China's largest medical device export category since 2012, and diagnostic equipment has registered the highest growth rate of any category since 2001.

Figure 2: While disposables were China's largest export category of medical devices for much of the past 15 years, they have been displaced by therapeutic devices since 2012 (billion \$)



Source: IHS Markit, Global Trade Atlas database (accessed September 22, 2017).
 Note: Underlying data for this figure can be found in appendix B.

Figure 3: Medium-to-high-value-added goods now make up the majority of China's total medical devices exports



Source: Compiled by author from IHS Markit, Global Trade Atlas database (accessed September 25, 2017).
 Note: Devices that have been categorized as low-tech include disposables, surgical instruments, intravenous diagnostic technologies, and parts of various products; medium-to-high-tech devices refer to therapeutic and diagnostic equipment. Devices which could not be clearly identified as low or high-tech were categorized as "other." These goods, which largely consisted of wheelchairs, were not included in the figure above, but accounted for less than 6 percent in each of the years covered.

Within these two categories of medical devices, growth was largely driven by a handful of products. For example, among therapeutics, sales of orthopedic implantable devices grew fastest, collectively increasing by 189 percent to \$555 million in 2011–16. At the same time, exports of diagnostic equipment (CTs, MRIs, and electrocardiographs) rose 37 percent to \$1.4 billion.

China's Market Growth Spurs the Domestic Industry

China's emergence as a global supplier of relatively high-tech medical devices reflects, in part, the increasing ability of local firms to supply the country's burgeoning market. As of 2016, China's healthcare market was valued at \$53.6 billion and ranked as the world's second largest behind the United States.⁶ In particular, China's rapid rate of urbanization, aging population, and increasing incidence of lifestyle-related afflictions has created substantial demand for various high-end categories of medical devices.⁷

For example, unprecedented urbanization⁸ in China has heightened the need for diagnostic technologies, pacemakers, dialysis systems, and intravenous diagnostic technologies. This trend reflects the various public health risks that tend to accompany city dwelling;⁹ for example, the number of diabetic patients in China has been estimated at roughly 110 million people, or 1 in 10 adults.¹⁰ Further, China's population of elderly people (those aged 65 and above)—already one of the world's largest—is fueling the rise in demand for orthopedic devices within the country. Various projections suggest that China could become the world's largest orthopedic device market within 10 years.¹¹ Elderly populations are generally the largest consumers of these devices, due to the degradation of the musculoskeletal system and loss of bone strength generally associated with aging.

At the same time, government policies have helped expand the growth of China's healthcare market. In an attempt to redress the country's historically inequitable healthcare system, China implemented healthcare market reforms in 2009. These have since been credited with improving the country's primary healthcare system, achieving near-universal health insurance through the expansion of basic health insurance, limiting out-of-pocket expenses, and reforming public hospitals. In accordance with these plans, China has steadily increased its healthcare spending, which reached a historic high of 6 percent of GDP in 2016.¹²

⁶ ITA, "China—Medical Devices," July 25, 2017; Dora et al., "Medtech May Be Emerging Markets' Next New Thing," March 2, 2017.

⁷ Luo, Wong, and Xia, "Winning in China's Changing Medtech Market," July 17, 2014.

⁸ Roxburgh, "Endless Cities," May 5, 2017.

⁹ Urbanization is often associated with many public health risks—including various non-communicable diseases such as lung cancer, cardiovascular disease, diabetes, and hypertension. These risks largely reflect the increased consumption of high-calorie, processed foods; the transition away from farming towards more sedentary occupations; and the relatively poor air quality that often accompanies city living. Torsekar, "U.S. Medical Devices," June 2014.

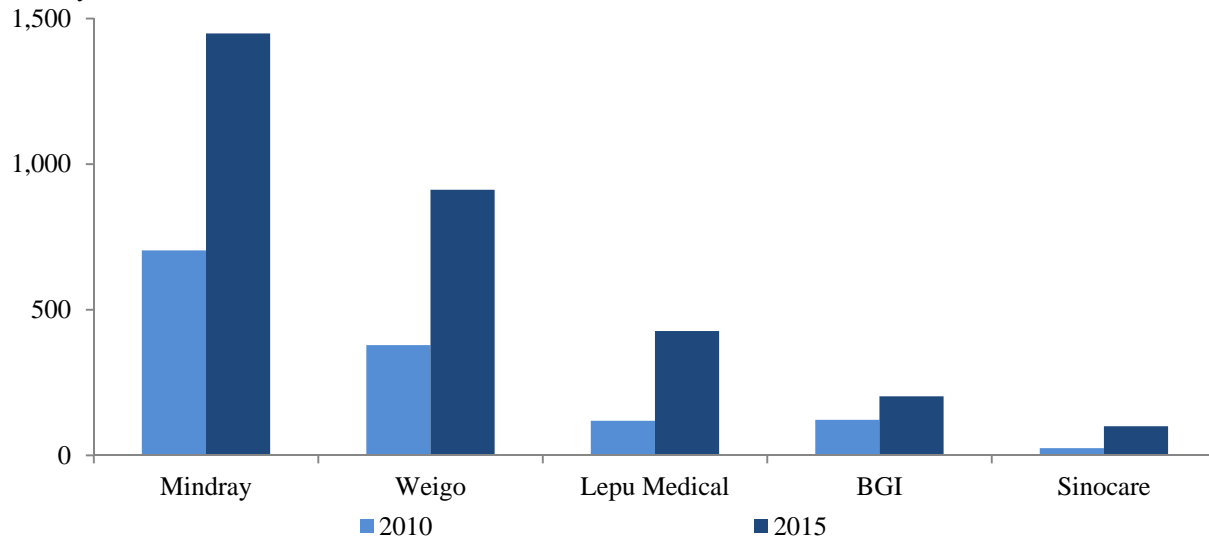
¹⁰ WHO, "Rate of Diabetes," April 6, 2016.

¹¹ Liu, "China's Market for Orthopedic Devices," n.d. (accessed October 10, 2017).

¹² EIU, *Medtech in China*, 2017.

MNEs still hold the majority share of China's high-end medical device market; of the estimated 15,000 manufacturers operating in the country, less than 13 percent of local firms make class 3 devices.¹³ While more than 80 percent of Chinese medical device manufacturers are small to medium-sized enterprises, only a handful of these firms have made substantial revenue gains in recent years (figure 3).

Figure 4: China's leading local medical device producers have substantially increased their revenues in recent years (million \$).



Source: Compiled by author from Dora et al., "Medtech May Be Emerging Markets' Next New Thing," March 2, 2017.

Much of this growth reflects the ability of these firms to translate their intimate knowledge of domestic consumers, access to distribution channels, and relatively low production costs into steadily increasing market shares within these segments.¹⁴ For example, three Chinese producers—Biosensors International, Lepu Medical, and MicroPort—currently account for 80 percent of all sales of drug-eluting stents, a relatively high-end therapeutic device. This situation stands in sharp contrast to 2004, when MNEs represented 90 percent of the Chinese market.¹⁵ Likewise, Chinese companies have increased their local market share to 50 percent for digital x-ray technologies after claiming zero market share in 2004.¹⁶ Further, Chinese firms are represented across a broad spectrum of medical technologies (table 1).

¹³ Ellerkamp, "Global Sourcing," October 18, 2017; Agarwal et al., *MedTech in Asia*, December 2015, 25.

¹⁴ Industry representative, interview by author, San Diego, CA (October 18, 2017).

¹⁵ Dora et al., "Medtech May Be Emerging Markets' Next New Thing," March 2, 2017.

¹⁶ Ibid.

Table 1: Leading Chinese medical device companies by production segment, 2014 revenues, and gross margins

Segment	Company	2014 Revenues (\$ million)	Gross margin (%)
Stents	Lepu Medical	267	63
	Microport	355	68
Orthopedic	Weigao	857	59
	Shanghai Kinetic	36	62
	PW Medtech	99	73
IVD	Kehua Biology	196	45
Diagnostic	Yuyue Medical	271	40
	Andon Health	69	31
Sterilizer	Shinva	1,015	23

Source: Agarwal et al., *Medtech in Asia*, December 2015, p. 25.

Government policies encourage local industry

Besides facilitating the growth of the market, China's recent government policies have also been directed towards improving the innovative and production capacity of local medical device firms.¹⁷ Broadly speaking, each of the three five-year plans that China has unveiled during 2001–16 has prioritized expanding domestic production of various high-tech goods—including those produced by the medical device industry.¹⁸ Moreover, China's 11th five-year plan specifically listed boosting exports of its high-tech industries as a priority.¹⁹

More specifically, in 2014, the China Food and Drug Administration (CFDA) announced expedited regulatory approvals for devices that it deemed innovative.²⁰ Qualifying devices are required to substantially improve upon the safety and performance of similar devices already in the market. Further, qualifying devices must contain novel technology that has been internationally recognized and that is patented in China.²¹

Since this policy's inception, Chinese companies have been its principal beneficiaries, accounting for more than 90 percent of the 117 devices approved under this expedited process.²² In contrast, MNEs represented less than 10 percent. The approved devices cover many of the high-value-added segments discussed earlier, including diagnostics (e.g., digital radiography)

¹⁷ EIU, *Medtech in China*, 2017; Agarwal et al., *MedTech in Asia*, December 2015, 22.

¹⁸ China's three most recent five-year plans—its 10th (2001–05), 11th (2006–10), and 12th (2011–15)—were unveiled during the period covered by this article. China.org, “The 10th Five-Year Plan,” n.d. (accessed November 11, 2017); Xinhua, “China Plans,” December 4, 2006; British Chamber of Commerce, “China's Twelfth,” 2011.

¹⁹ Xinhua, “China Plans,” December 4, 2006.

²⁰ Innovative devices are products that substantially improve on the safety and performance of those already in the market. EIU, *Medtech in China*, 2017; Luo, Wong, and Xia, “Winning in China's Changing Medtech Market,” July 17, 2014.

²¹ Luo, Wong, and Xia, “Winning in China's Changing Medtech Market,” July 17, 2014.

²² EIU, *Medtech in China*, 2017.

and therapeutic devices (e.g., interventional cardiology). Roughly 80 percent of these fast-track approvals have occurred in coastal cities of eastern China.²³

Chinese companies have also tended to be advantaged by another recently introduced CFDA policy requiring manufacturers of most class 2 and 3 devices to carry out local clinical trials regardless of the origin of the device, before they can be sold in China.²⁴ This policy represents a considerable departure from the former system, which permitted firms that had obtained market clearance in other countries to sell in China without undergoing additional regulatory procedures.²⁵ The former regime benefited MNEs in that they could sell devices in multiple markets while only submitting clinical data once. Because the costs of collecting these data range from \$1 million to \$1.5 million, and because it can take three to five years to obtain market clearance, MNEs may be discouraged from selling high-tech goods in China's market under the new policy.²⁶

Another significant new policy that has benefited indigenous medical device producers is the "Made in China 2025" initiative. The plan, which was announced in 2015, prioritizes the expansion of high-tech medical device production.²⁷ According to "semiofficial" targets, China intends domestic production to supply 50 percent of the country's market with local production by 2020 and 70 percent by 2025.²⁸ Similarly, among the priorities listed in China's 12th five-year plan from the Ministry of Science and Technology is the advancement of local manufacturers in high-tech medical technology sectors, such as diagnostic imaging.²⁹

China becomes a leading international supplier of higher-tech devices

The growing innovative capacity of Chinese firms, coupled with their ability to meet the needs of local consumers, has produced opportunities for them to serve the higher-end segments in other emerging markets. Much like China, these markets tend to be price sensitive, and Chinese-produced devices can retail at anywhere from 10 to 70 percent of the price of multinational firms, depending on the product.³⁰ In one example, local Chinese firms charge roughly 40 percent lower prices than do MNEs for drug-eluting stents.³¹ These price disparities largely reflect the absence of various nonessential but costlier elements commonly found in pricier MNE-produced medical devices (e.g. black and white ultrasound machines versus color). Some Chinese companies are also able to draw their competitive advantages in emerging markets from investments made within these countries. For example, China's largest medical device company,

²³ Ibid.

²⁴ Luo, Wong, and Xia, "Winning in China's Changing Medtech Market," July 17, 2014.

²⁵ Giger, "China: Challenges and Opportunities," June 20, 2017.

²⁶ Ibid.

²⁷ Medtec, "Made in China 2025," December 30, 2015; Wubbeke et al., *Made in China 2025*, December 2016.

²⁸ Wubbeke et al., *Made in China 2025*, December 2016.

²⁹ Luo, Wong, and Xia, "Winning in China's Changing Medtech Market," July 17, 2014.

³⁰ Dora et al., "Medtech May Be Emerging Markets' Next New Thing," March 2, 2017; Gross, "Be Very Careful," December 13, 2016.

³¹ Luo, Wong, and Xia, "Winning in China's Changing Medtech Market," July 17, 2014.

Mindray, has established local operations in India, employs local workers, and has performed extensive research on the Indian market.³²

Further, many of the factors that are driving China's medical device market growth are mirrored in other rapidly growing healthcare markets, such as India. This suggests that Chinese firms that are successful at supplying the local market can apply these strategies to serving consumers in these other countries, many of which share a similarly high disease burden and aging demographics. In one example, during 2009–16, China emerged as India's third-largest medical device supplier (behind the United States and Germany) and is currently India's leading provider of CT scanners, representing half of the \$69 million India spent on imports of these high-tech devices during 2016.³³ Much like China, India's healthcare market is characterized by substantial rates of non-communicable diseases.³⁴

At the same time, China has become a leading supplier of high-tech medical goods to developed markets as well. For example, Japan—the world's third-largest medical device market—has commonly been supplied by countries with mature industries, such as the United States and the European Union. However, during 2015, China overtook Germany to become Japan's second-largest supplier of MRI devices, behind the United States.³⁵ Further, in the relatively developed healthcare markets within Europe (France, Germany, Italy, Spain, and the UK), Biosensors, a Chinese-owned firm, is one of the leading providers of drug-eluting stents, a niche market.³⁶

Moreover, although MNEs maintain a much larger international presence, local Chinese companies are growing at a much faster rate. China's five largest local producers have achieved an average compound annual growth rate (CAGR) of 6–32 percent during 2010–15. In contrast, CAGRs for five of the leading Western MNEs operating in China ranged from less than 1 percent to 6 percent during this time.³⁷ On the other hand, MNEs earn much higher revenues than Chinese firms, reflecting the MNEs' greater maturity. For example, Medtronic, the world's largest pure-play medical device manufacturer, earned nearly \$30 billion in 2015, while China's largest medical device firm, Mindray, garnered less than \$2 million during that year.³⁸

³² Dora et al., "Medtech May be Emerging," March 2, 2017.

³³ IHS Markit, Global Trade Atlas database (accessed October 5, 2017).

³⁴ Upadhyay, "An Overview," March 31, 2012.

³⁵ IHS Markit, GTA (date accessed October 5, 2017).

³⁶ Dora et al., "Medtech May Be Emerging Markets' Next New Thing," March 2, 2017; Gross, "Be Very Careful," December 13, 2016.

³⁷ Ibid.

³⁸ Ibid.

Appendix A

HTS codes for medical devices and categories

Table A-1: Medical devices by HTS description and product categories

HS Products	Description	Category
9019	Mech-Ther, Massage, Psych Test, Ozone App Etc, Pts	Therapeutic
901890	Instr & Appl F Medical Surgical Dental Vet, Nesoi	Surgical Instruments
3005	Bandages Etc Coated Etc Or In Retail Medic Etc Fm	Disposables
901839	Med Needles. Nesoi, Catherers Etc And Parts Etc	Disposables
300630	Opacifying Preparations For X-Ray Examinations Etc	Diagnostic
901831	Syringes, With Or Without Needles; Pts & Access	Surgical Instruments
901812	Ultrasonic Scanning Apparatus	Diagnostic
8713	Carriages For Disabled Persons, Motorized Or Not	Other
901819	Electro-Diagnostic Apparatus Nesoi, And Parts Etc.	Diagnostic
901813	Magnetic Resonance Imaging Apparatus	Diagnostic
902212	Computed Tomography Apparatus	Diagnostic
902110	Orthopedic Or Fractre Appliances, Parts & Accessor	Therapeutic
902140	Hearing Aids	Therapeutic
401519	Gloves, Except Surgical Etc, Vulcan Rubber, Nesoi	Disposables
871420	Parts & Accsries Of Carriages For Disables Persons	Parts
401511	Surgical & Med Glove, Vulcanize Rubber	Disposables
902190	Oth Artificial Pts Of The Body & Pts & Accessories	Therapeutic
902121	Artificial Teeth And Parts And Accessories	Therapeutic
902214	Apts Base On X-Ray, Medical, Surgical, Vetnry, Nesoi	Diagnostic
901849	Inst & Appln For Dental Science, & Pts & Acc, Nesoi	Surgical Instruments
901832	Tubular Metal Needles & Needles For Sutures & Parts	Disposables
3822	Composite Diagnostic/Lab Reagents, Exc Pharmaceut	IVD
300650	First-Aid Boxes And Kits	Disposables
902131	Artificial Joints And Parts And Accessories Therof	Therapeutic
901850	Other Ophthalmic Instruments & Appliances & Parts	Surgical Instruments
841920	Medical, Surgical Or Laboratory Sterilizers	Surgical Instruments
900140	Spectacle Lenses Of Glass	Surgical Instruments
901811	Electrocardiographs, And Parts And Accessories	Diagnostic
902139	Artificial Joints & Parts & Accessories Therof, Nes	Therapeutic
902230	X-Ray Tubes	Diagnostic
901841	Dental Drill Engines And Parts And Accessories	Therapeutic

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901814	Scintigraphic Apparatus	Diagnostic
902129	Dental Fittings And Parts And Accessories	Therapeutic
300640	Dental Cements And Other Dental Fillings Etc	Therapeutic
901820	Ultraviolet Or Infrared Ray Apparatus, & Pts & Acc	Diagnostic
3821	Prepared Culture Media For Development Of Microorganisms	IVD
300691	Appliances Identifiable For Ostomy Use	Therapeutic
900130	Contact Lenses	Therapeutic
611510	Graduated Compression Hosiery	Disposables
902221	Appts Base On Alpha,Beta,Etc Radiation,Medical,Etc	Diagnostic
902213	Appts Base On X-Ray For Dental, Uses, Nesoi	Parts
902150	Pacemakers For Stimulating Heart Muscles	Therapeutic

Source: IHS Markit, Global Trade Atlas (date accessed September 22, 2017); Bamber, *Costa Rica in the Medical Devices Global Value Chain*, August 2013.

Note: "IVD" refers to Intravenous Diagnostics.

Appendix B

China's medical device exports during 2001–16

Table A-2: China's medical device exports by specific categories, 2001–16, (billion \$)

Year	Disposables	Surgical Instruments	Therapeutic devices	Diagnostic	Other	Parts
2001	471,185,523	207,229,964	321,068,359	116,006,040	42,300,627	15,002,943
2002	528,615,798	237,265,644	404,048,941	142,907,843	70,097,734	24,218,743
2003	670,751,039	319,819,475	523,123,433	210,554,715	121,070,354	43,616,612
2004	881,966,058	454,159,166	680,237,570	276,709,230	134,236,961	44,366,958
2005	1,068,375,447	563,971,393	1,004,188,380	383,871,607	186,172,105	55,650,443
2006	1,244,678,906	749,907,587	1,291,566,443	573,674,004	218,198,056	73,452,698
2007	1,547,673,563	970,571,916	1,618,850,179	865,773,688	288,831,460	111,370,298
2008	2,035,752,740	1,290,004,101	1,934,376,035	1,196,514,803	361,102,854	112,283,503
2009	1,902,930,648	1,327,724,840	1,952,803,435	1,329,933,043	349,608,070	116,544,120
2010	2,157,594,032	1,628,238,100	2,229,497,791	1,675,767,119	422,606,163	150,429,037
2011	2,736,102,648	1,808,796,884	2,664,571,021	2,022,056,068	461,520,991	168,143,493
2012	2,981,333,657	1,942,719,743	3,340,811,544	2,328,947,433	486,458,823	187,528,649
2013	3,194,376,627	2,165,253,627	3,493,052,560	2,632,132,600	472,115,534	195,290,985
2014	3,378,641,233	2,452,285,596	3,680,700,066	2,810,659,662	538,728,371	228,990,881
2015	3,410,593,093	2,571,352,812	4,046,077,501	2,947,525,936	547,902,557	236,009,771
2016	3,340,288,540	2,640,654,579	4,269,777,626	2,926,633,249	540,507,290	226,811,439

Source: IHS Markit, Global Trade Atlas (date accessed September 22, 2017).

Appendix C

China's Composition of Medical Device Exports

Table A-3: China's low-tech, medium-high-tech, and other categories of medical device exports, 2001–16, (%)

Year	Low-tech	Medium-High Tech	Other
2001	59%	37%	4%
2002	56%	39%	5%
2003	55%	39%	6%
2004	56%	39%	5%
2005	52%	43%	6%
2006	50%	45%	5%
2007	49%	46%	5%
2008	50%	45%	5%
2009	48%	47%	5%
2010	48%	47%	5%
2011	48%	48%	5%
2012	45%	50%	4%
2013	46%	50%	4%
2014	46%	50%	4%
2015	45%	51%	4%
2016	45%	52%	4%

Source: IHS Markit, Global Trade Atlas database (accessed September 22, 2017).

Note: The “other” category includes wheelchairs, motorized or otherwise, as well as parts for x-rays and dental applications that have not otherwise been classified in the HTS schedule. The ambiguity of these product categories prevented a categorization into either low-, medium-, or high-tech goods.

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