



Healthcare Insights for India

Top 5 countries for import and export of medical devices

Report by:

India Health 
By Informa Markets

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Definition of a medical device

According to the World Health Organisation (WHO) definition, a 'medical device' means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease,
- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- Investigation, replacement, modification, or support of the anatomy or of a physiological process,
- supporting or sustaining life,
- Control of conception,
- Disinfection of medical devices
- Providing information by means of in vitro examination of specimens derived from the human body;

and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.

India's medical device market in numbers

- India among the Top 20 markets for medical devices in the world
- 4th largest medical device market in Asia
- India's medical device market size expected to reach \$50 billion by 2025
- Diagnostic imaging, dental products and consumables are expected to grow at a CAGR of 7.1 %, 7.4 % & 7.1 %, respectively during 2015-2020
- Orthopaedic prosthetics and patient aids segments to be the two fastest-growing verticals by 2020 and are projected to grow at a CAGR of 9.6 % and 8.8 %, respectively
- Imports of medical devices in 2019 grew by 24 % YoY and exports grew by 29 % YoY
- There are 750 - 800 domestic medical devices manufacturers in India

Industry scenario in India

According to the latest commentary from Invest India, the country's national investment promotion and facilitation agency, currently, India is counted among the top 20 global medical devices market and is the 4th largest medical devices market in Asia after Japan, China and South Korea. The medical devices industry in India has the potential to grow at 28 % per annum to reach US\$ 50 billion by 2025.

In India, medical devices are segregated into six major segments, of which equipment and instruments (surgical and non-surgical) form the largest portion (53 %) of the pie.

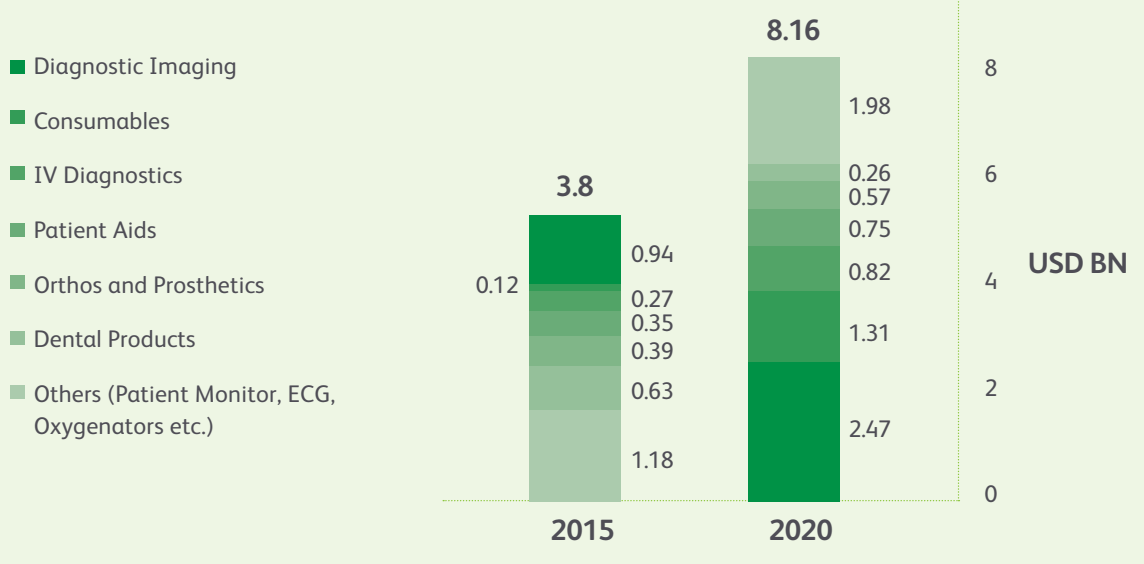
Data from India's commerce ministry, compiled by the Association of Indian Manufacturers of Medical Devices (AiMeD) - an umbrella organisation representing the medical devices industry - shows that imports of medical devices in 2019 grew by 24 % year-on-year (YoY) and, in comparison, exports grew by 29 % YoY.

Both imports and exports have registered good growth rates compared to the previous three fiscal years. While imports grew 12%, 7% and 13% during the previous three years, exports clocked 5%, 14% and 1% growth.

The growth in imports was led by product categories such as diagnostic items, ultra-sonogram machines, MRI and ECG apparatus, syringes with needles, suture needles, digital thermometers, malaria diagnostic kits, and hearing aids.

Domestic companies are largely involved in manufacturing low-end products for local and as well as international consumption. There are 750-800 domestic medical devices manufacturers in India, with an average investment of US\$ 2.3-2.7 million and an average turnover of US\$ 6.2-6.9 million. Around 65% of the manufacturers are mostly domestic players, operating in the consumables segment, and catering to local consumption with limited exports.

Segment wise market share of medical devices



Source: <http://www.makeinindia.com/article/-/v/sector-survey-medical-devices>



With the liberalising of government policies, up to 100 % Foreign Direct Investment (FDI) is permitted in medical devices through the automatic route. Foreign direct investment in medical device manufacturing sector is permitted without any prior approval from the government, allowing business to quickly scale-up existing operations by infusing capital or engage in time-sensitive strategic acquisitions.

During the period between April 2000 and March 2017, US\$ 1.57 billion worth FDI came into the country. Taking advantage of this lucrative opportunity, an increasing number of MNCs are setting up their manufacturing bases in India.

According to Export.gov, India imports nearly 50 %

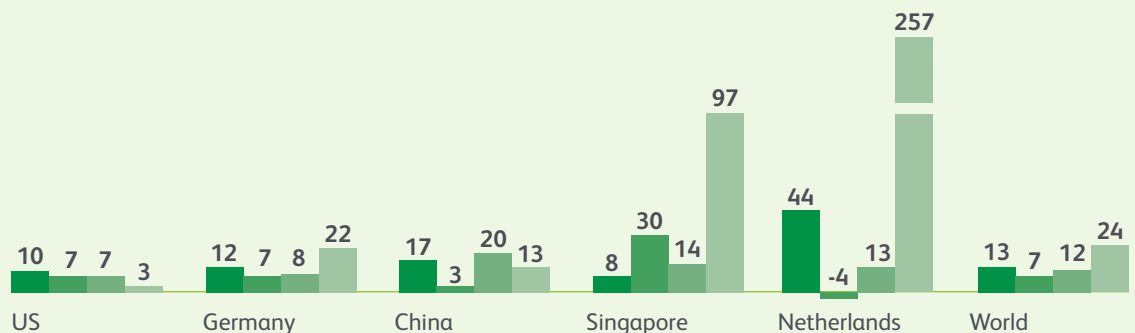
of its medical devices and barriers to entry are low compared to other industries. India offers opportunities for the direct supply of high technology, specialised medical equipment, products and systems. Particularly in view of the relatively low customs duty rates (9.2% -15 %), combined with an increasing number of healthcare centres specialising in advanced surgery.

Medical Devices, including surgical instruments, attract 6 % central excise duty and 5 % Value Added Tax (VAT) and along with CST, octroi, entry tax etc. comes to more than 13 % . With the new Goods and Services Tax regime, the rate is 12 % . This new rate is advantageous to achieve lower costs of manufacturing, and thereby proving beneficial to consumers.

Top 5 medical device & equipment import countries for 2019

Top nations from where devices were imported

■ -FY16 ■ -FY17 ■ -FY18 ■ -FY19
(% YoY growth rates)



Source: Ministry of Commerce, compiled by AiMeD

There are a range of Medical Device Clusters that have emerged due to supportive state-level policies as well as the availability of skilled labour. The top five countries from where medical devices were imported included the US, Germany, and China, as well as the

Netherlands and Singapore. Growth in imports from the US, however, fell in 2019 with a 3% growth, compared to 7% in 2018. Germany saw double-digit growth of 22% over the previous year, while China saw 13% growth, Singapore 97%, and Netherlands 257%.

Import value of medical devices for top 10 countries in 2018

Rank	Country	Import value US\$
1	China	\$14,975,495
2	Germany	\$9,976,390
3	USA	\$3,973,937
4	Other Asian countries	\$3,336,553
5	Italy	\$3,004,459
6	Poland	\$1,972,707
7	Indonesia	\$1,762,649
8	United Kingdom	\$1,489,454
9	France	\$1,045,821
10	Switzerland	\$782,018

Source: United Nations Commodity Trade Statistics Database





Regulatory environment

To ensure quality healthcare, in October 2005, the Government of India increased the list of medical devices covered under the Drugs and Cosmetics Act of 1940, bringing several categories of implantable devices under regulatory control. This list was further revised in October 2018, bringing several additional categories of implantable devices under regulatory control.

The new Medical Device Rules, 2017, have eliminated the need for constant re-approval of manufacturing and import licenses, and these licenses have now been made valid for perpetuity unless the license is suspended, terminated or surrendered.

The rules are applicable for:

1. Substances used for in vitro diagnosis (IVD) and sterile surgical dressings, surgical bandages, surgical staples, surgical sutures, ligatures, blood and blood component collection bag with or without anticoagulant.
2. Substances including mechanical contraceptives

(condoms, intrauterine devices, tubal rings), disinfectants and insecticides.

3. Devices notified from time to time.

The rules have been drafted with the intention to distinguish medical devices from pharmaceuticals for improved and well-defined regulation. The key highlights of the rules are:

- Redefining 'medical devices', making it more comprehensive and easy to comprehend.
- Introduction of risk-based classification system for class-wise regulation.
- Single window clearance (online portal) for applications for import, manufacture, sale or distribution and clinical investigation.
- Establishment of product standards for medical devices for being conformed.
- Rationalisation of timelines for obtaining licenses required to market medical devices.
- Consolidation of registration certificate and import license into a single license.
- New regulatory framework for clinical investigation of medical device.

Growth drivers for the medical device market

• Nascent indus

Importing more than 90 % of sophisticated devices, the domestic industry has a huge scope for R&D capacity

• Aeging population

With an ageing population and life expectancy to cross 70 years by 2022, there is a need for home-based healthcare devices

• Growing population

According to the United Nations, India's population is set to touch 1.45 billion by 2028, making it the world's most populous nation

• Increasing disposable income

8 % of India's population will earn more than US\$ 12,000 per annum by 2026

• Industrial parks

Four medical devices parks in India are currently under development

• Government commitment

There are new rules and regulatory processes for the medical devices sector in which 100 % FDI allowed.

There are also measures being undertaken to correct unfavourable duty structure

The challenges

Much like in any country, there are certain challenges in doing business of medical devices in India that must be considered.

The first and foremost challenge is price control. The Government of India controls prices of certain medical devices by either fixing a price at which they may be sold under a formula or by restricting the ability of the marketer of the medical device to increase its price by more than a prescribed percentage at any given time.

The second challenge is the **presence of multiple regulators**, which may make simple tasks, such as rectification of erroneous declaration on the label, quite a tumultuous affair.

The third challenge is presence of **outdated laws** that do not permit manufactures and importers of medical device to promote their product directly to the customer as cures for certain prescribed conditions and illnesses.

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Healthcare has become one of India's largest sectors both in terms of revenue and employment. India Health presents an opportunity to all stakeholders in search of a platform that facilitates business interaction, learning and development, and access to the right healthcare entities, authorities and associations in a fast-emerging economy.

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