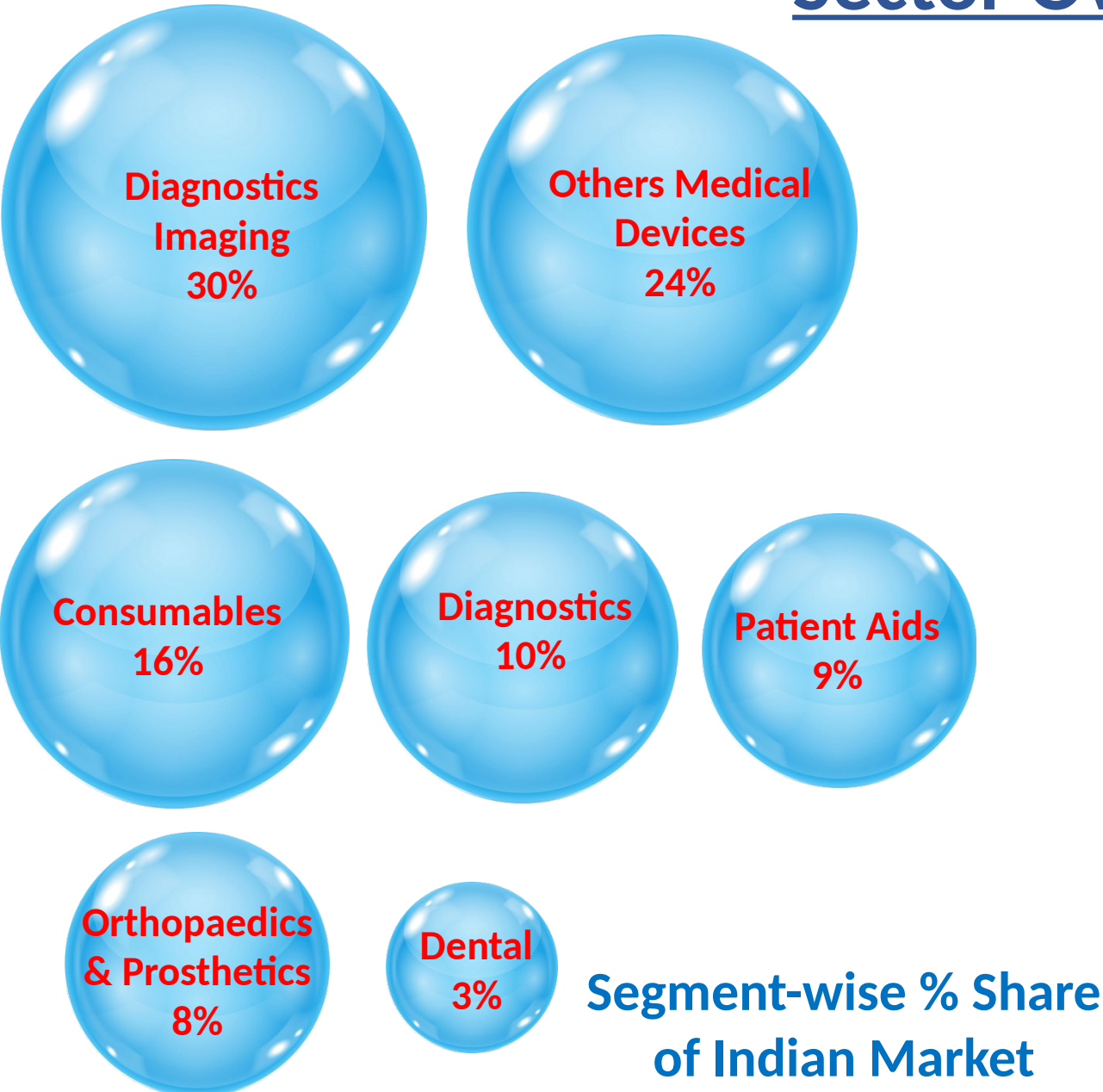


EEPCINDIA
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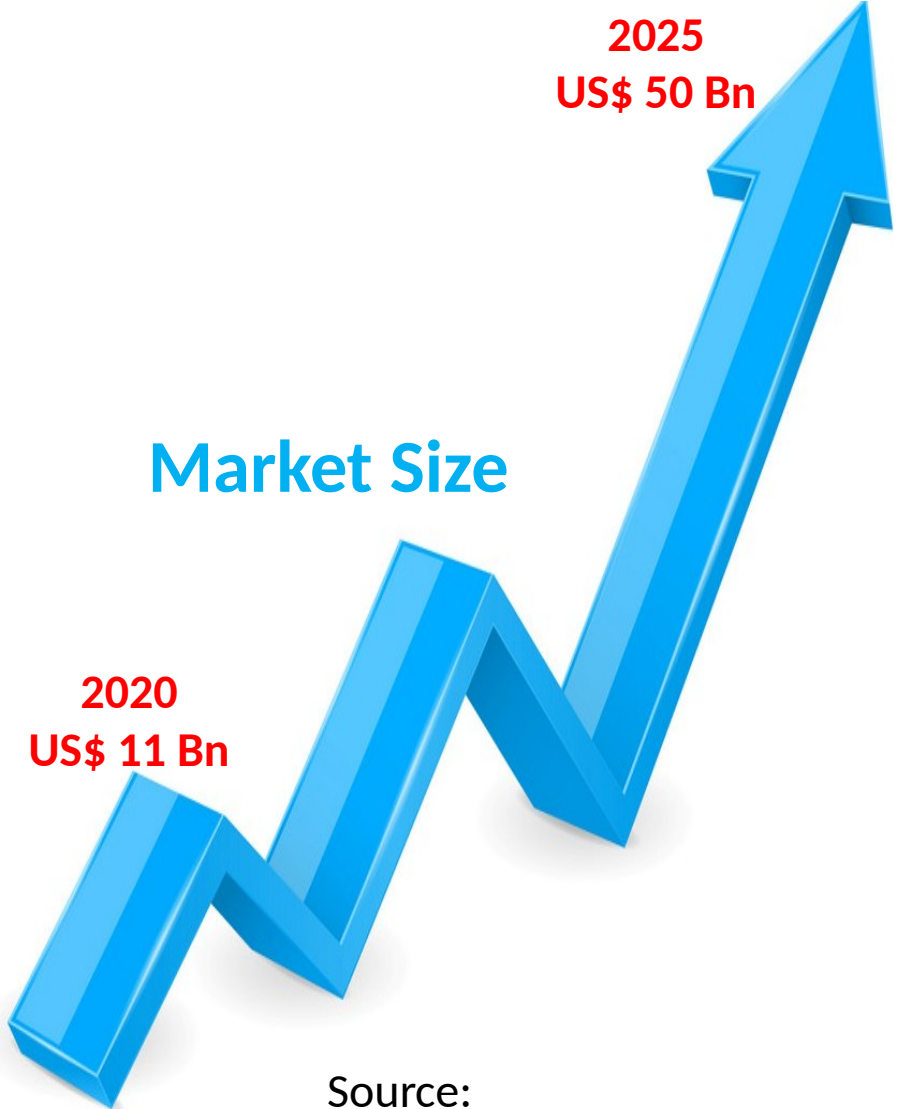


INDIAN MEDICAL DEVICES -AN OVERVIEW

Sector Overview



Segment-wise % Share of Indian Market



Source:
www.investindia.gov.in
www.makeinindia.com

Trade Overview

Exports 2018-19: USD 2.1 billion

Imports 2018-19: USD 6.2 billion

Import dependency 75-80%

Since April 2000, FDI to the tune of \$2.1 bn has been invested in the sector

Top countries

Singapore, United States, Europe, and Japan are key investors

Major sectors for investment

Equipment & Instruments, Consumables and Implants have attracted most FDI

Major overseas investors in India

3M, Abbott, Baxter, Boston Scientific, GE Healthcare, Johnson & Johnson

Domestic Production Viz Exports Patterns

Product	Domestic Consumption	Exports
Consumable	40%	60%
Diagnostics & Imaging Equipment	53%	47%
Instruments & Appliances	50%	50%
Patient Aid & other	65%	35%

Some Major Export & Import Products

	Top Export Product Groups		Top Import Product Groups
1	Needles, catheters, cannulae		Needles, catheters, cannulae
2	X-ray tubes		X-ray generators
3	Electro-diagnostic apparatus		Chromatographs and electrophoresis instruments
4	X-ray generators		Apparatus based on the use of X-rays
5	Orthopaedic or fracture appliances		Ultrasonic scanning apparatus
6	Artificial parts of the body		Ophthalmic instruments and appliances
7	Electro-cardiographs		Artificial parts of the body
8	Magnetic resonance imaging apparatus		Ozone therapy, oxygen therapy, aerosol therapy, artificial respiration or other therapeutic respiration apparatus
9	Ultrasonic scanning apparatus		Magnetic resonance imaging apparatus
10	Tubular metal needles and needles for sutures		Artificial joints for orthopaedic purposes

Russia as an export destination for Indian medical devices

- Russia is among the top destinations of India's medical device exports.
- Russia is also an important market for India since it acts as springboard to CIS Region
- 60% of the India's medial device exports to CIS region is to Russia
- India's exported USD 25 million USD of medical devices to Russia in Yr. 2019-20. There has been a steady growth in India's medical device exports to Russia.
- Indian companies are facing various challenges while exporting to Russia like lengthy registration process & regulations, language barrier etc.
- MRA has also been signed between India and Russia to remove technical barriers to trade.

Glimpse of few Indian companies in the medical device sector

Some of India's top medical device companies like Meril Life Sciences, Tranasia Biomedical, Griportho, Mitra Industries and Trivitron are exporting to Russia.

Company Name	Product Details
Bio Medical Devices	S. S.Wound Drainage System Trocar (Redon Needle); & Chest Drainage Catheter Trocar.
Applied Optical Technologies Pvt Ltd	Optic Fiber Cable, LED Light Source, Headlight, Endoprobe, LASER fiber
Sterile World Technologies LLP	Sterilization Packaging Material and Medical Devices
SCEPTRE MEDICAL INDIA PVT LTD	HEMODIALYSIS CATHETER KIT (SINGLE, DOUBLE , TRIPLE & LONG TERM) , BLOOD TUBING, TRANSDUCER PROTECTOR , AV FISTULA NEEDLE , BIOPSY GUN
Ayka Medical Inc.	Sterilization reels Sterilization pouches Chemical Indicators Biological indicators
"Earthveda Healthcare" Ayurveda Research and Life Sciences LLP	Immunity Tablet (Immunity Booster) , Immunity Plus Capsule(Immunity Booster), DM Care Tablet (Diabetes Care), Ayulith Tablet (Renal Care), E Clear Tablet & Syrup (RTI), Breath Tablet & Syrup (Asthma Care), Instaliv Tablet & Syrup (Liver Care), Latifol Capsule (Male Sexual Booster), Pacifica Tablet (Plant based Calcium Supplement)
Godrej Group	Medical refrigerators for vaccines & blood

India's regulatory environment for medical devices

Overview of India's legal and regulatory framework for medical devices

- The main regulatory framework for the import, manufacture, sale of medical devices in India is the Drugs and Cosmetics Act, 1945 and the Medical Device Rules, 2017.
- Earlier only 37 categories of medical devices, notified by the Government of India under the regulatory framework.
- Risk based classification of all the medical devices - Class A (low risk), Class B (low moderate risk), Class C (moderate high risk) and Class D (high risk) as decided by the Central Drugs Standard Control Organization (CDSCO).
- Product standards for medical devices and Market entry for foreign manufactured medical devices through import license.

Recent Amendments

- Revised definition of Medical Devices under the Drugs Act notified to include all medical device intended for use in human beings or animals would qualify as drugs under section 3(b)(iv) of the Drugs Act with effect from 1st April 2020.
- The revised definition of medical device would result in bringing medical equipment such as knee implants, CT scan, MRI equipment, defibrillators, dialysis machine, PET equipment, X-ray machine etc.
- New registration requirement of medical devices under the Medical Devices (Amendment) Rules, 2020:-
 - Medical devices which have been additionally notified as drugs effective from 1st April 2020
 - Registration on voluntary basis for a period of 18 (eighteen) months
 - Exemption and relaxations for the medical devices falling within the newly notified definition
 - To meet certified quality standards

INDIAN MEDICAL DEVICES INDUSTRY: MANUFACTURING CLUSTERS

6 14

Gujarat

Pharmaceuticals

3M, Bayer AG, Meril Life Sciences, Envison Scientific, Invent Bio Med, Sahjanand Medical Technologies

Maharashtra

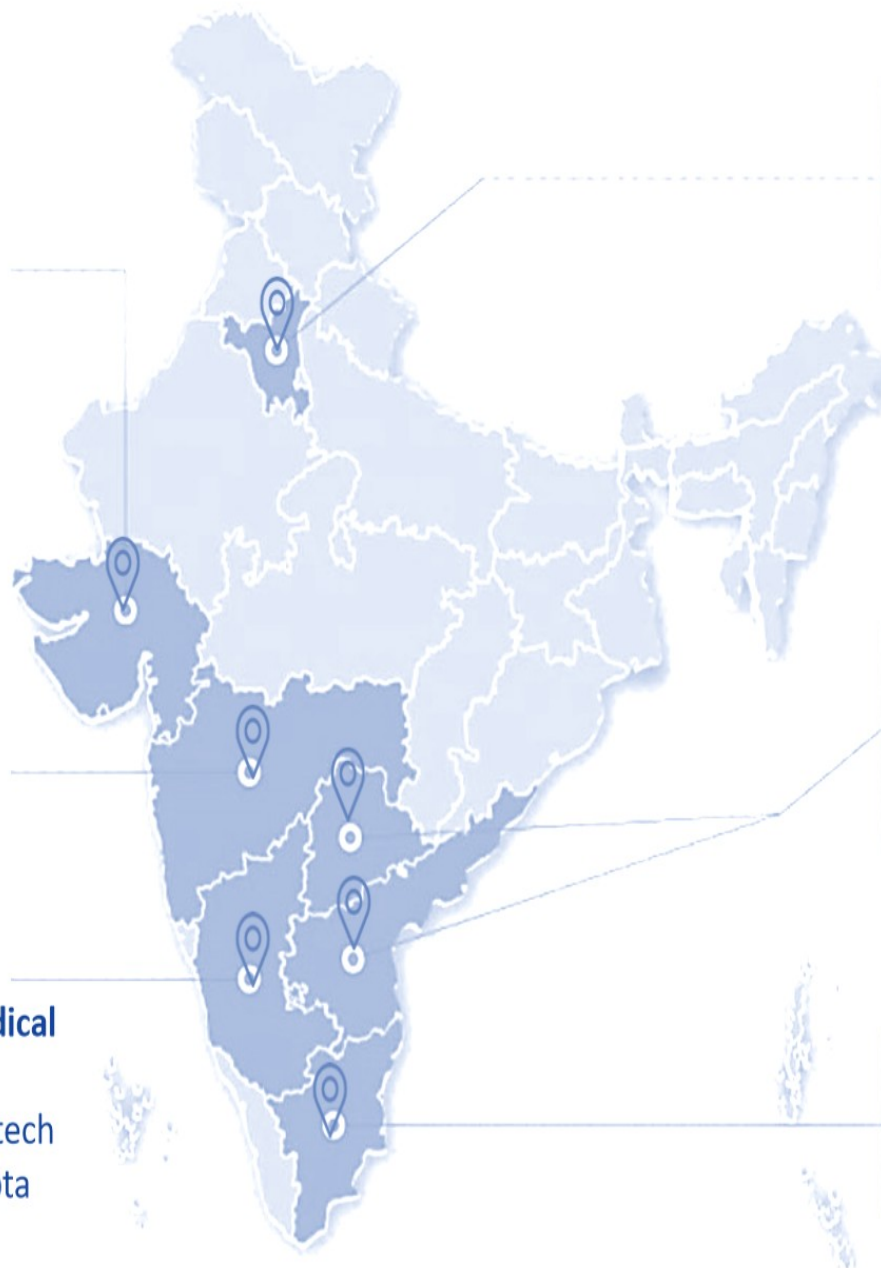
Pharmaceuticals

Johnson and Johnsons, Phillips Healthcare, Siemens, Trivitron Healthcare, Danaher Corp., Remi Laboratories

Karnataka

Insulin Pens, Stents & Implants, Medical Electronics

GE Healthcare, Biocon, Medived, Bigtech Labs, Prognosis Medical, Skanray, Opta Circuits



Haryana

Low-End Medical Consumables

Boston Scientific Corporation, Beckton Dickinson India

Andhra Pradesh, Telangana

Medical Electronics

St. JuMedtronic, des Medical, Relisys Medical Devices, B Braun

Tamil Nadu

Medical Electronics

Trivitron Healthcare, Opto Circuits, Perfint Healthcare, Phoenix Medical Systems, Cura Healthcare, Schiller, Roc

**Over 800
Manufacturers**

**250+ Health Tech
Startups**

**Presence of
many Global
Giants**

Factors promoting the growth of medical device sector in India

Identified as a Sunrise sector in the Make in India campaign 2014	Duties Correction - Inverted duties for 78 devices (Jan 2016) and 5% cess added on the basic duty on (March 2020)
Quality - Launch of ICMED Quality certification by Quality Council of India	Regulatory Framework - Separate act under drafting to regulate all devices under MDR'17
Manufacturing Facility - Setting up of Medical Device parks in the country to create a conducive cost effective manufacturing environment	Support Services - Provide facilitation services to investors through agencies like EEPC India & Invest India
100% FDI is allowed in the sector.	Cluster Development: Several medical devices industrial clusters have been developed across India
Improvement in R&D Academia & Industry Collaboration Framework like Kalam Institute of Healthcare	Emphasis on Innovations & R&D & Low Cost Hi Tech Technologies

Impact of COVID 19 Pandemic on Indian Medical Devices Sector

- Indigenization of several Critical Care, Low Cost Ventilators, PPE Kits and Sanitization Technologies, making India emerge as one of the largest producers of these devices
- Opportunities of more robotics and automation integration in production processes
- Improvement in R&D Academia and Industry collaborations
- Indian government to take measures to reduce dependency on China

EEPC India activities in Medical Device sector

- Nodal agency to coordinate trade promotion activities
- Leading Brand India Engineering campaign for the sector globally
- Developed an e – product catalogue for the sector
- Advocates policy & regulations
- Showcases India at the leading International expositions such as at Arab Health, Asia Pharma etc
- Organises RBSM, Trade Delegations etc

Thank you



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