INDIAN MEDICAL DEVICES - AN OVERVIEW
Sector Overview

**Market Size**
- **2020**
  - US$ 11 Bn
- **2025**
  - US$ 50 Bn

**Segment-wise % Share of Indian Market**
- **Diagnostics Imaging**
  - 30%
- **Others Medical Devices**
  - 24%
- **Consumables**
  - 16%
- **Diagnostics**
  - 10%
- **Patient Aids**
  - 9%
- **Orthopaedics & Prosthetics**
  - 8%
- **Dental**
  - 3%

**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:

<table>
<thead>
<tr>
<th>Product</th>
<th>Domestic Consumption</th>
<th>Exports</th>
</tr>
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<tbody>
<tr>
<td>Consumable</td>
<td>40%</td>
<td>60%</td>
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<tr>
<td>Diagnostics &amp; Imaging Equipment</td>
<td>53%</td>
<td>47%</td>
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<tr>
<td>Instruments &amp; Appliances</td>
<td>50%</td>
<td>50%</td>
</tr>
<tr>
<td>Patient Aid &amp; other</td>
<td>65%</td>
<td>35%</td>
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<tr>
<td>Top Export Product Groups</td>
<td>Top Import Product Groups</td>
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<tr>
<td>--------------------------------------------------</td>
<td>----------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>1. Needles, catheters, cannulaes</td>
<td>Needles, catheters, cannulae</td>
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<td>2. X-ray tubes</td>
<td>X-ray generators</td>
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<tr>
<td>3. Electro-diagnostic apparatus</td>
<td>Chromatographs and electrophoresis instruments</td>
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<tr>
<td>4. X-ray generators</td>
<td>Apparatus based on the use of X-rays</td>
<td></td>
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<tr>
<td>5. Orthopaedic or fracture appliances</td>
<td>Ultrasonic scanning apparatus</td>
<td></td>
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<tr>
<td>6. Artificial parts of the body</td>
<td>Ophthalmic instruments and appliances</td>
<td></td>
</tr>
<tr>
<td>7. Electro-cardiographs</td>
<td>Artificial parts of the body</td>
<td></td>
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<tr>
<td>8. Magnetic resonance imaging apparatus</td>
<td>Ozone therapy, oxygen therapy, aerosol therapy, artificial</td>
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<tr>
<td></td>
<td>respiration or other therapeutic respiration apparatus</td>
<td></td>
</tr>
<tr>
<td>9. Ultrasonic scanning apparatus</td>
<td>Magnetic resonance imaging apparatus</td>
<td></td>
</tr>
<tr>
<td>10. Tubular metal needles and needles for sutures</td>
<td>Artificial joints for orthopaedic purposes</td>
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</table>
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.
Some of India’s top medical device companies like Meril Life Sciences, Tranasia Biomedical, Griportho, Mitra Industries and Trivitron are exporting to Russia.

### Glimpse of few Indian companies in the medical device sector

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

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
IN INDIAN MEDICAL DEVICES INDUSTRY: MANUFACTURING CLUSTERS

**Gujarat**
- Pharmaceuticals
  - 3M, Bayer AG, Meril Life Sciences, Envisor 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
<table>
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<th>Factors promoting the growth of medical device sector in India</th>
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<td>Identified as a Sunrise sector in the Make in India campaign 2014</td>
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<td>Quality – Launch of ICMED Quality certification by Quality Council of India</td>
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<td>Manufacturing Facility – Setting up of Medical Device parks in the country to create a conducive cost effective manufacturing environment</td>
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<td>100% FDI is allowed in the sector.</td>
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<td>Improvement in R&amp;D Academia &amp; Industry Collaboration Framework like Kalam Institute of Healthcare</td>
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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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