Medical Devices
...The Next Big Story
After IT & Pharma

The 9 Billion+ $ Investment Opportunity
AiMeD is an umbrella association of Indian Manufacturers of Medical Devices. With a primary membership of over 350 manufacturers and 200+ associate members representing the interest of over 1200 manufacturers.

The dark cloud of COVID-19 has one silver lining - 'Make In India' of medical devices has become a valued entity.

Currently working closely with govt. of India i.e Dept. of Pharmaceuticals, ministry of commerce etc as a facilitator between the government and the medical device manufacturers for ramping up capacity and addressing production bottlenecks in this National emergency.
### TOP INDIAN MANUFACTURERS

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<th>DISPOSABLES</th>
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<th>ELECTRONICS</th>
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<td>HMD</td>
<td>Romsons</td>
<td>Trivitron Healthcare</td>
<td>Midmark</td>
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<td>Kanam Latex</td>
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<td>G. Surgiwear</td>
<td>BL Lifesciences</td>
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<td>MRK</td>
<td>Tynor Orthotics</td>
<td>ITPL</td>
<td>Phoenix</td>
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## TOP INDIAN MANUFACTURERS

### IMPLANTS
- SMT
- Meril
- Appasamy
- Aurolab
- Biorad Medisys
- Pitkar

### DIAGNOSTICS
- Transasia
- Trivtron
- Meril
- Agappe
- Mitra Industries

### INSTRUMENTS
- ASCO
- Alan Electronic
- HMD
- Quality Needles
- EndoMed Technologies
EXPORT SUMMARY OF MEDICAL DEVICES

FY 2015-16
94.74 Billion RUB

FY 2019-20
153.8 Billion RUB

Electronics & Equipments
40.9%

Consumables
32.8%

Disposables
18.2%

Implants
3.2%

Electronics & Equipments
43.6%

Consumables
28.1%

Disposables
18.9%

Implants
4.1%

Reagent

Surgical Instruments
MAKE IN INDIA - ACHIEVEMENTS

• Kalam Institute of Healthcare established at Vizag
• ICMED (Indian Certification of Medical Devices by QCI).
• Medical Devices Rules 2017
• Ethical marketing - price caps on stents and knee implants
• Medtech parks at Vizag & Hyderabad
• Indian Biomedical Skills Consortium
• Amendment of legal metrology (packaging commodities) rules
• Executed workshops on CE, ICMED, MDR 17 in multiple cities
BEFORE & AFTER COVID COMPARISON (TOTAL NUMBER OF MANUFACTURERS)
Problems & Challenges being faced in Exporting to Russia

EXPENSIVE REGISTRATION
Delayed results from tests from local labs. A new registration can take 1.5 years

CLINICAL DATA REQUIRED
For class IIA, IIB, III, their regular RZN require clinical data for trials within Russia

TIME CONSUMING
Very expensive and time consuming process for all documents to be translated in Russian language.

HIGH COST
Very high cost between $15000-$30000 for moderate risk.
Problems & Challenges being faced in Exporting to Russia

- DIFFERENT FROM EUROPEAN SYSTEM
  Russian classification system similar but not identical to European system.

- DOES NOT FOLLOW ISO STANDARD
  Russia does not follow ISO standards but they follow Roszdravnadzor Order 735 & GOST 51609-2000.

- LENGTHY OWNERSHIP TRANSFER
  Takes a long time to transfer the registration to a new importer even after the consent of existing importer.

- COMPLEX MEDICAL DEVICE MARKET
  Large but fragmented medical device market. Local contacts essential for successful commercialisation.
Problems & Challenges being faced in Exporting to Russia

**NOT HARMONIZED WITH INTERNATIONAL STANDARD**

Technical documentation as Russian GOST standards are not in sync with other international standards and do not recognise CE, US FDA 510K marking.

**HIGH DUTIES**

Restriction on sending samples for business promotion.

**DELAYED PAYMENT TRANSFER**

Payments from Russia usually take 10-12 days to get credited in account.

**RESTRICTED ACCESS TO PUBLIC TENDER**

Restricted access to public health tenders and plan to reduce import dependence on 111 medical product groups.
EASE OF DOING MEDICAL DEVICE BUSINESS IN RUSSIA

**FAST TRACKED REGISTRATION**
ICMED/ISO 13485 & CE certifications may be fast tracked for registration

**QUICK PROCESS**
Registration process may be completed in max 6-9 months.

**NO RESTRICTION**
No restriction in sending samples from India

**LOWERED REGISTRATION COST**
Registration cost maybe lowered for Indian companies
TALK TO US!

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