

RAJIV NATH | FORUM COORDINATOR | AIMED

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

The 9 Billion+ \$ Investment Opportunity

AIMED

ASSOCIATION OF INDIAN MEDICAL DEVICES

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.



AIMED

TOP INDIAN MANUFACTURERS

DISPOSABLES

- HMD
- Medico Electrodes
- Kanam Latex
- G. Surgiwear
- MRK

CONSUMABLES

- Romsons
- Polymedicure
- Healthium
- BL Lifesciences
- Tynor Orthotics

ELECTRONICS

- Trivitron Healthcare
- Allengers Medical
- BPL
- Skanray
- ITPL

EQUIPMENTS

- Midmark
- Remi
- Cura
- Shivani
- Phoenix

TOP INDIAN MANUFACTURERS

IMPLANTS

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

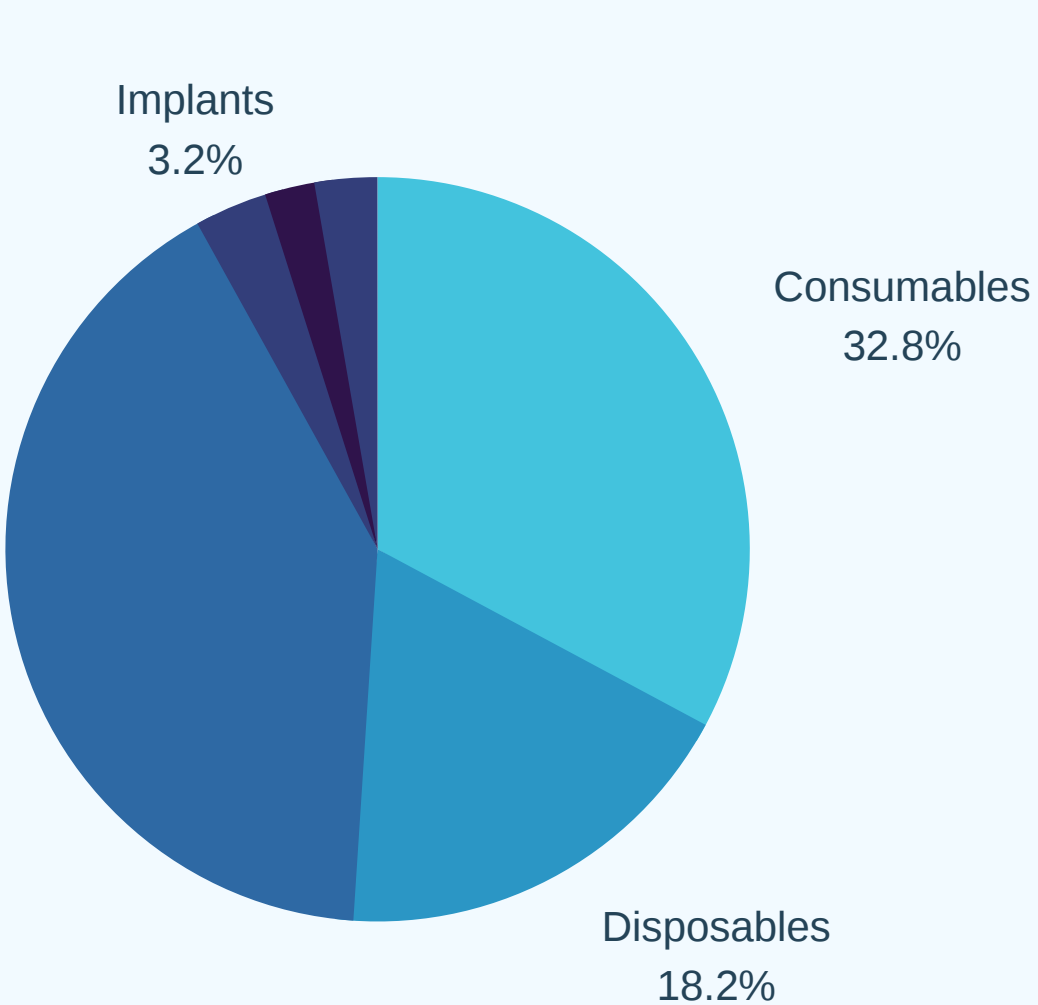
DIAGNOSTICS

- Transasia
- Trivtron
- Meril
- Agappe
- Mitra Industries

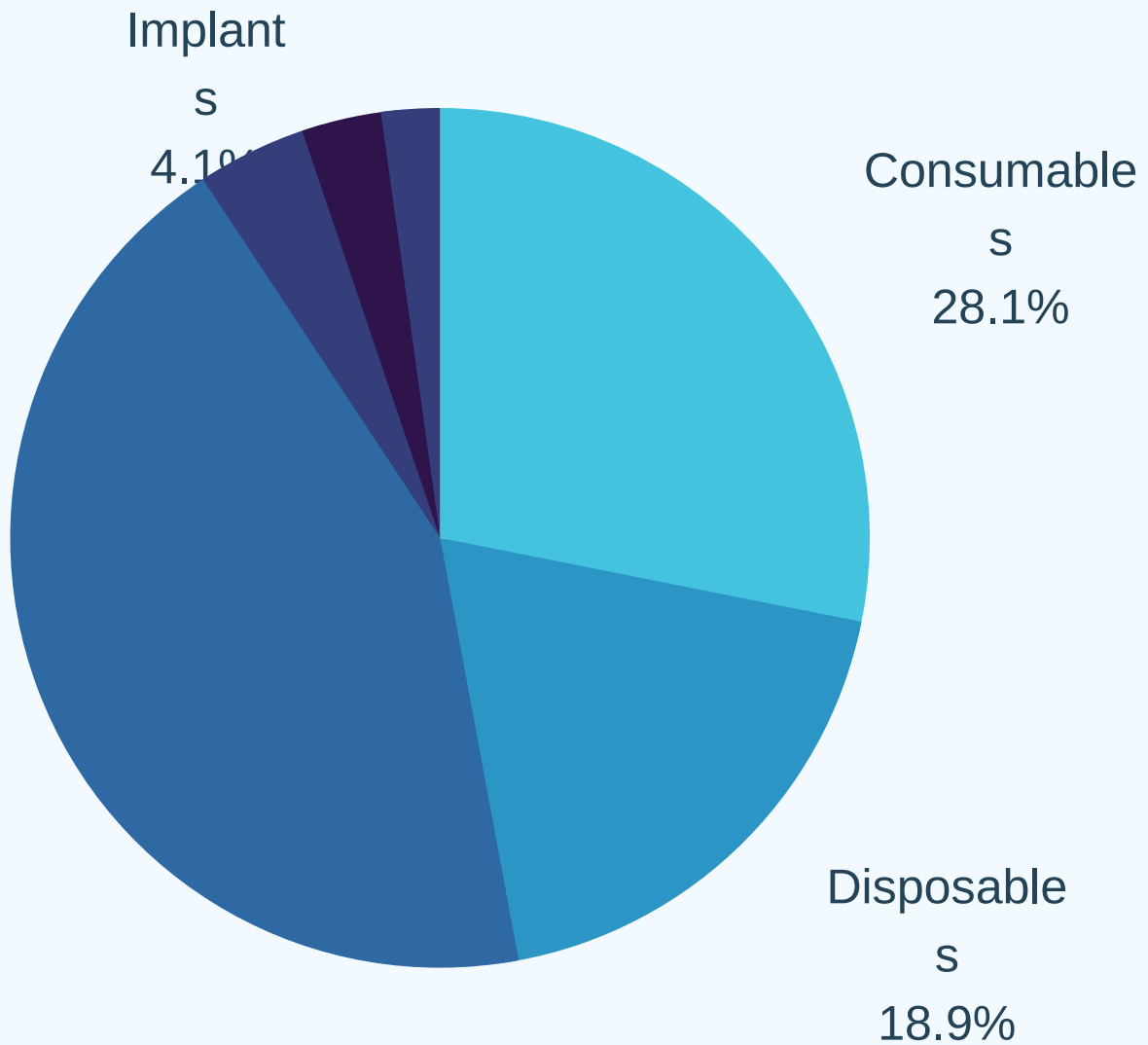
INSTRUMENTS

- 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

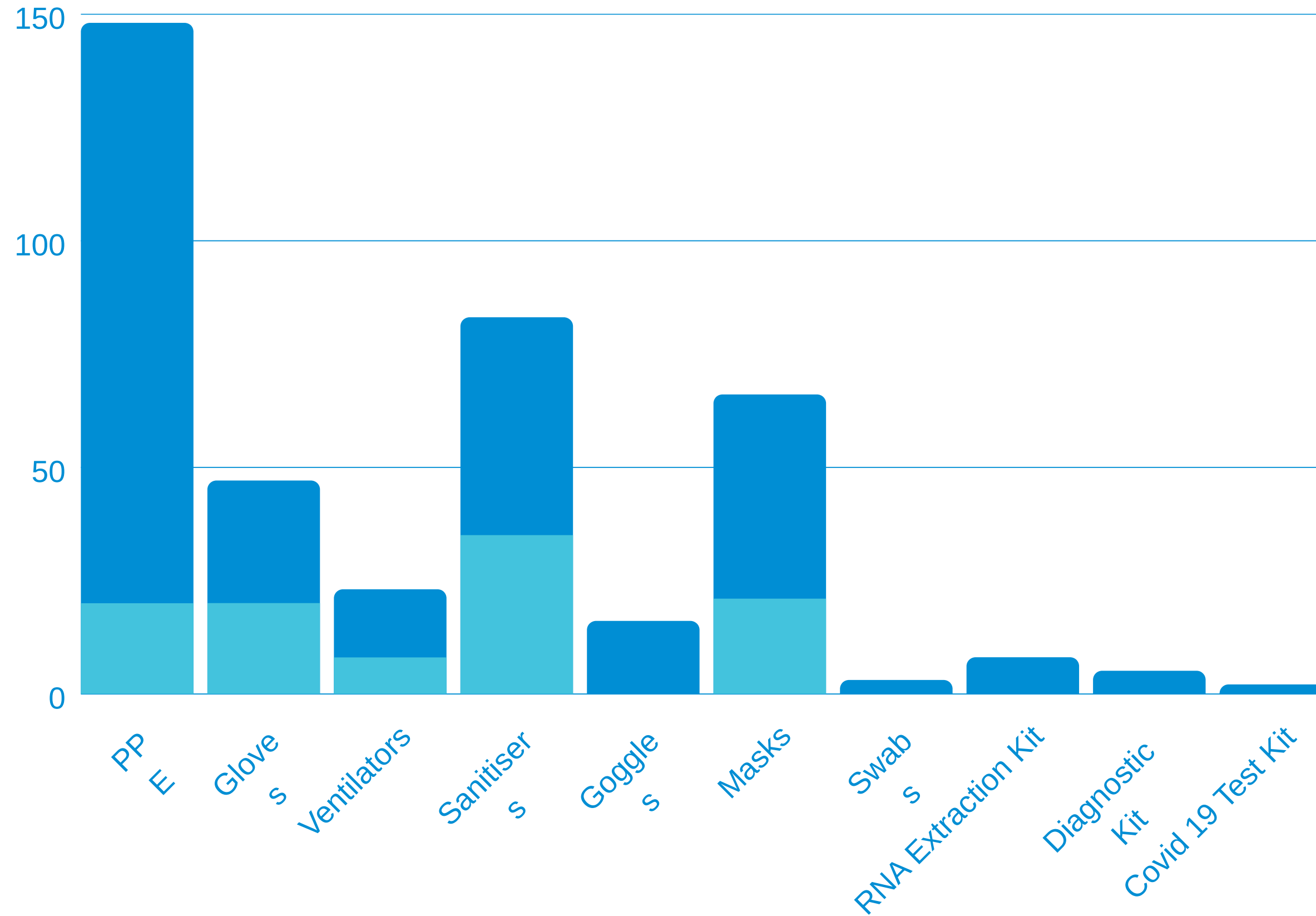
IVD
 Reagent
 Surgical
 Instruments



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

Registration ^{COST} maybe lowered for Indian companies

TALK TO US!

RAJIV NATH

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