TIC COUNCIL

THE INDEPENDENT VOICE OF TRUST

TIC Council Webinar
Shaping India's Medical Devices Regulatory Framework: Global Best Practices and Priorities

28-29 October 2021

Technical Session: The Evolving Medical Device Quality & Regulatory Framework

Chair

Dr. R.P. Singh
Secretary
General, QCI

Moderator

Dr. Shailendra Singh
TUV SUD Pvt Ltd.,
India

Technical Session: The Evolving Medical Device Quality & Regulatory Framework

Speakers

Dr. Jitendra Sharma
Managing Director
and CEO,
AMTZ

Rajesh Maheshwari,
CEO, NABCB

Ravi Singh,
Member, TICC, Med Device
WG

Dr. Jitendra Sharma
Managing Director and
CEO,
AMTZ

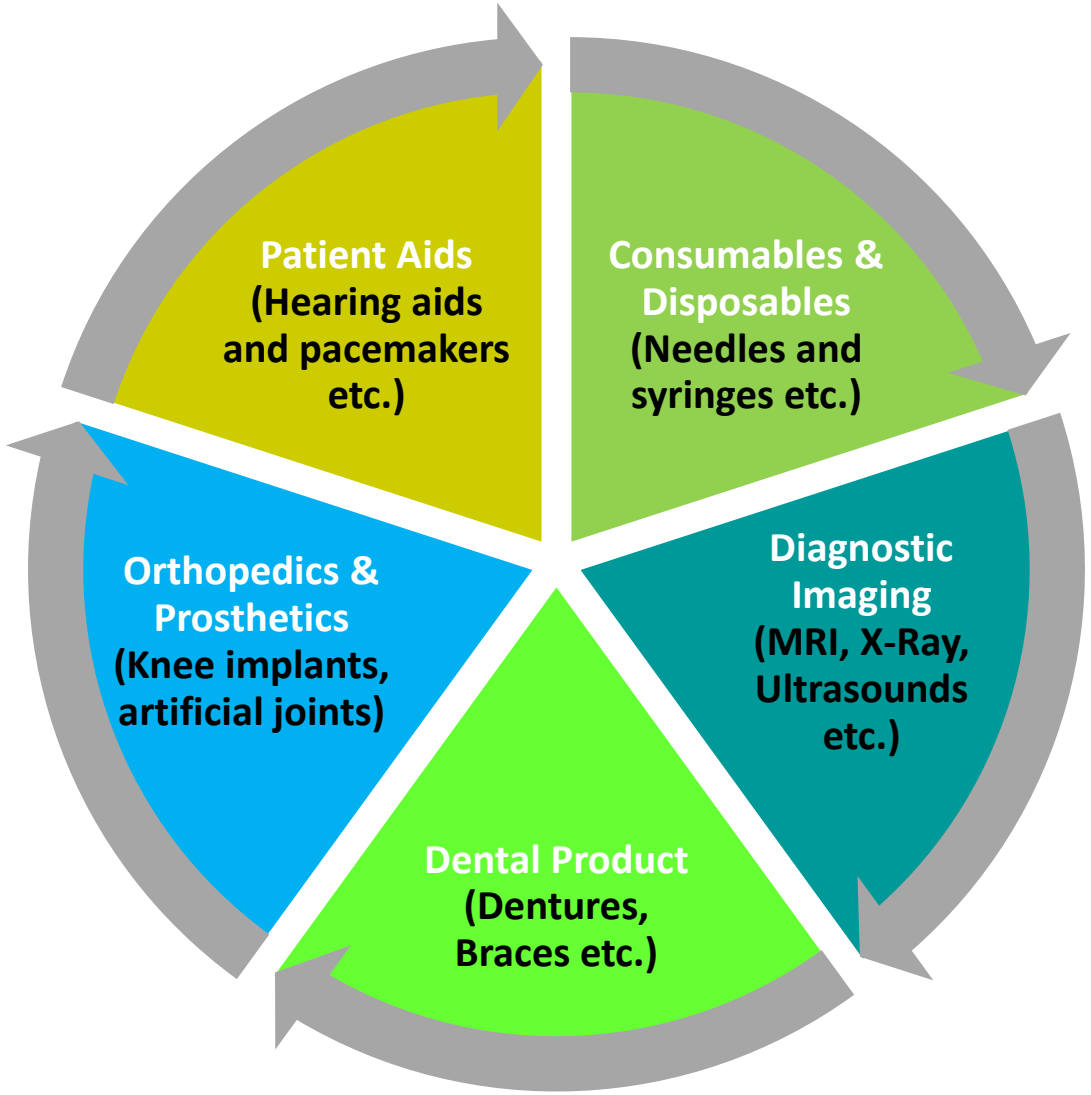
Rajesh Maheshwari,
CEO, NABCB

National Accreditation Board for Certification Bodies (NABCB)

Accreditation: Supports Implementation of Medical Devices Regulations

Introduction

- Around **65% of the manufacturers** in India are mostly **domestic players** operating in the consumables segment.
- Large Multinational Corporations lead the **high technology end of the Medical Devices market** with extensive service networks.
- There are **750–800 domestic Medical Devices manufacturers** in India, with an **average investment of USD 2.3–2.7 Mn** and an **average turnover of USD 6.2-6.9 Mn**.

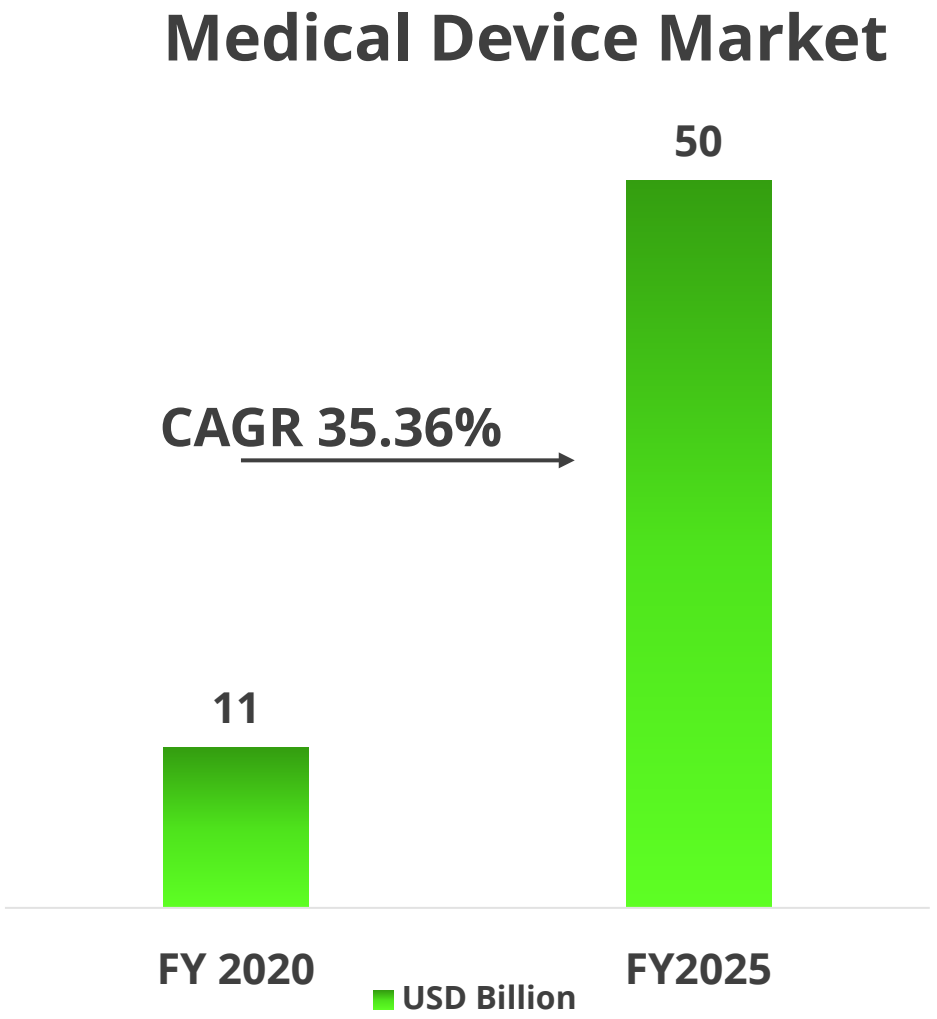


Segregation of Medical Devices

https://www.investindia.gov.in/sector/medical-devices

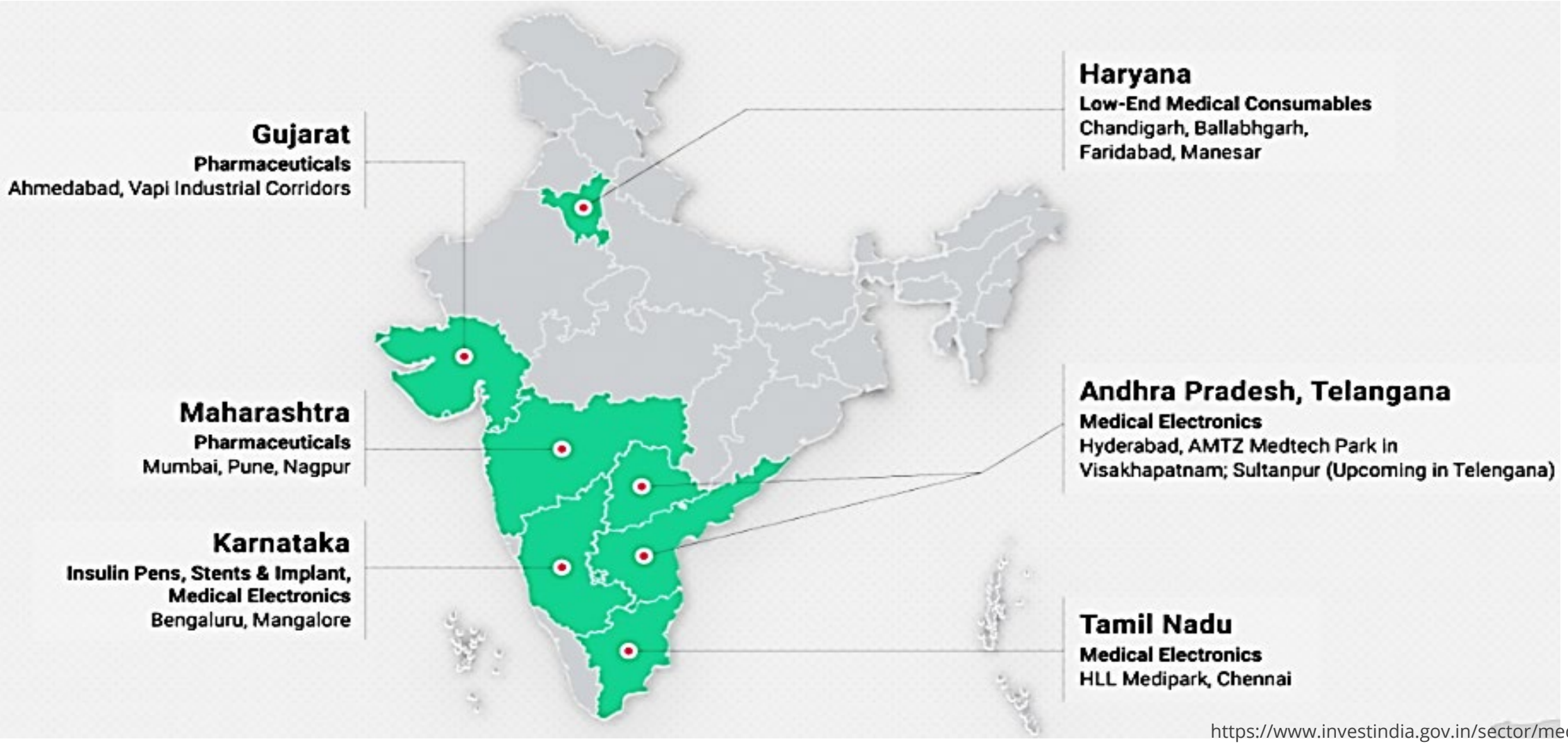
Market Scenario

- The Indian medical devices sector is estimated to be worth **USD 10 billion** (approx.) in 2021.
- India has an overall **75-80% import dependency** on medical devices, with export at **USD 2.1 billion in 2019** and is expected to rise at **CARG of 29.7%** to reach **USD 10 billion in 2025**.
- The **US**, **Germany**, **China**, **Brazil**, **Iran** etc. are a few key countries that import Indian medical devices.



IBEF-Medical-Devices-August-202

Manufacturing Clusters for Medical Devices



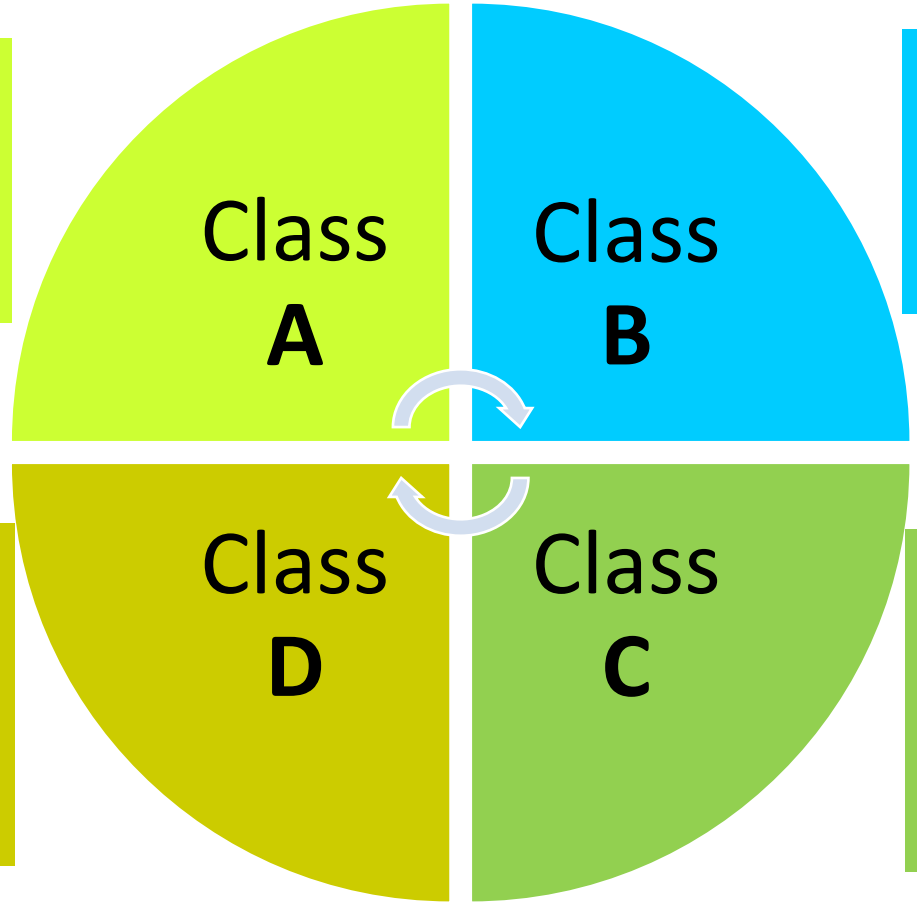
https://www.investindia.gov.in/sector/medical-dev

Medical Devices Classification

Under the Medical Device and IVD Regulations, the Health Ministry of India has divided medical devices into following categories:

Low Risk

Surgical dressings, umbilical occlusion devices, bolster sutures, alcohol swabs etc.



Low Moderate Risk

Endoscopic forceps, vial adapters, suction cups and catheters, feeding tubes etc.

High Risk

Coronary stents, cardiac catherization kits, cardiovascular, intravascular diagnostic catheters etc.

Moderate High Risk

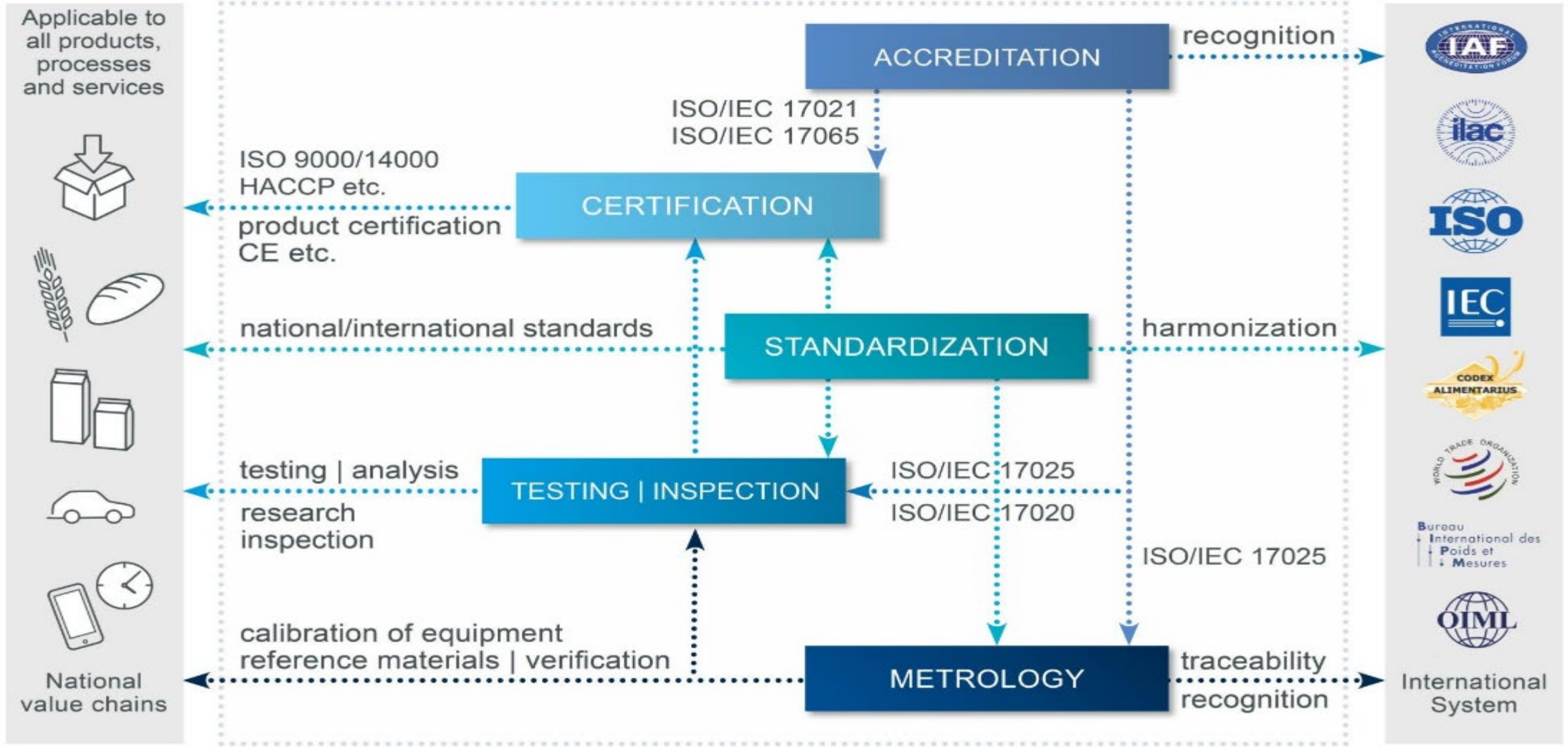
Anesthesia conduction filter, introducer sheath, microcatheter, imaging catheter, colonic stents, pancreatic instruments etc.

IBEF-Medical-Devices-August-2021

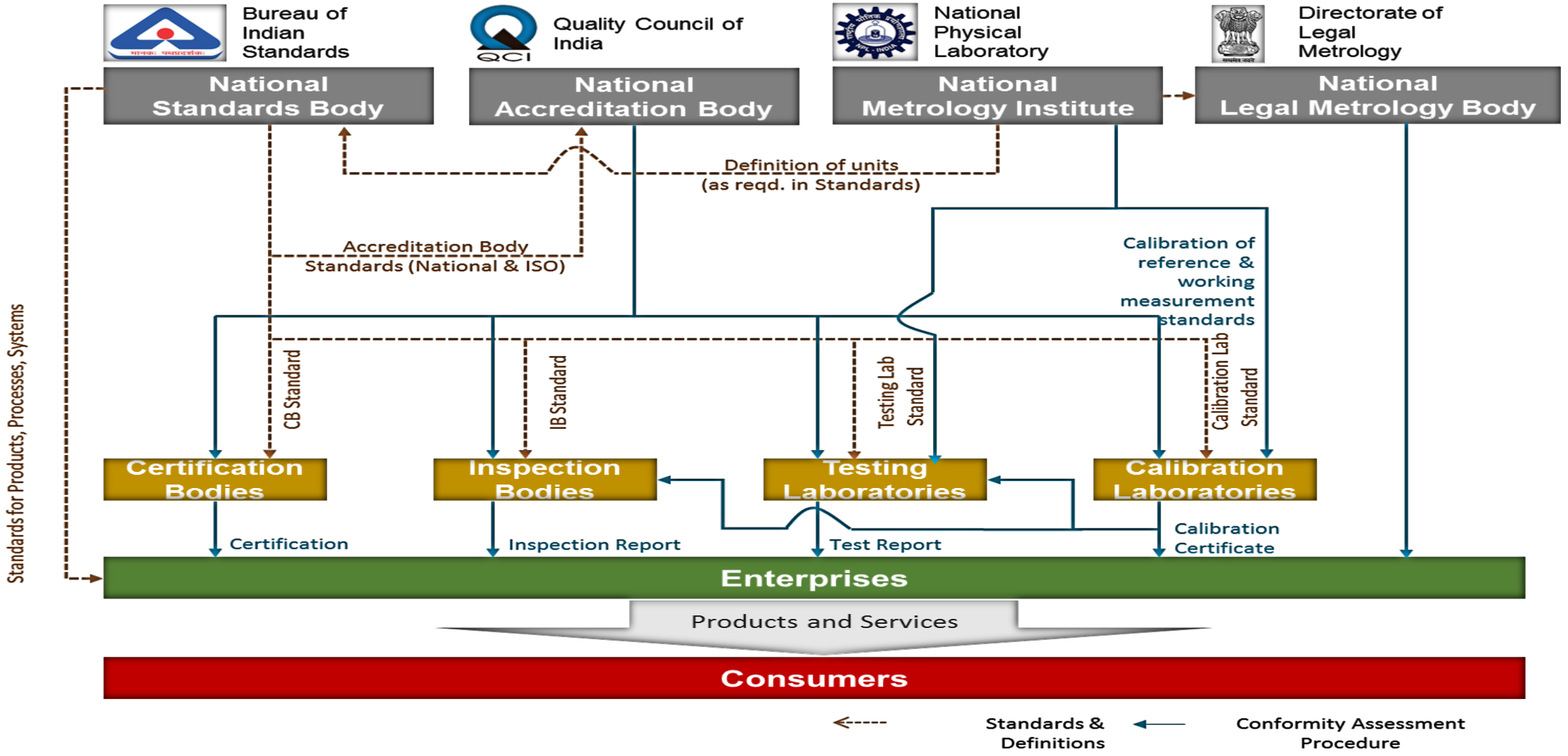
Regulatory Ecosystem for Medical Devices in India

- In India, medical devices are **regulated under the Drugs and Cosmetics Act**.
- Medical devices are regulated by the **Central Drugs Standard Control Organization (CDSCO)**, an agency of the Ministry of Health and Family Welfare.
- CDSCO has **Central Licensing Authority (CLA)** and **State Licensing Authority (SLA)** with responsibility for Licensing to Import, Manufacture for sale or for distribution and sale, stock, exhibit or offer for sale.
- CLA is responsible for **all Import Devices Licensing** and **Class C & Class D Medical Devices Manufacturing**.
- SLA is responsible for **Class A & Class B Medical Devices Manufacturing**.

The International Ecosystem for Quality



The Quality Infrastructure in India



Quality Council of India

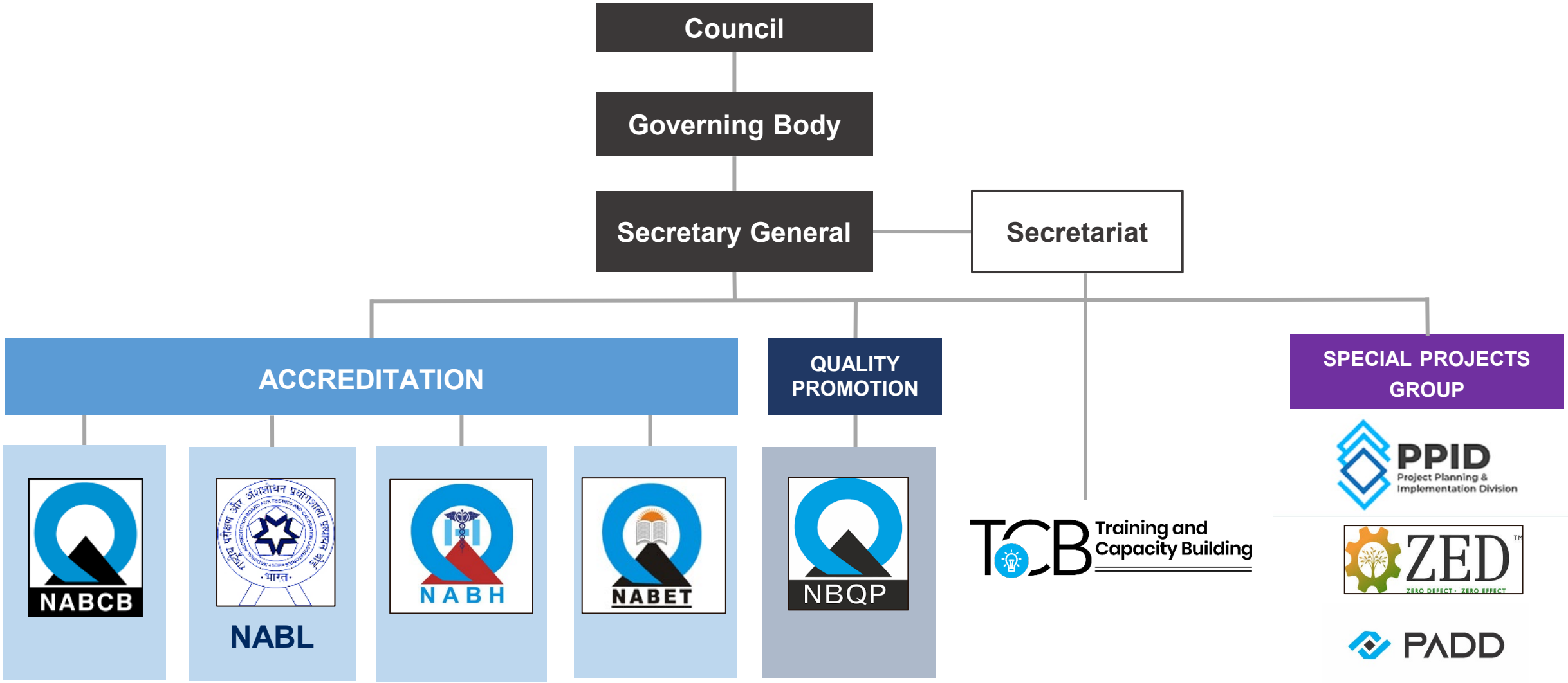
About QCI

- Set up in Jan 1997 by the Government of India with ASSOCHAM, CII & FICCI
- QCI is an independent autonomous organization under the Department for Promotion of Industry and Internal Trade (DPIIT), Ministry of Commerce & Industry, Govt. of India.
- QCI was established as the National Accreditation Body and to lead a quality movement by undertaking a National Quality Campaign
- Chairman of QCI is appointed by the Hon'ble Prime Minister of India

QCI Mandate

- **Provide Accreditation Framework in the country**
- **Spread quality movement in India**
- **Provide right and unbiased information on Quality & related Standards**
- **Represent India's interest in International fora.**
- **Help establish quality of Indian products & services**

The Ecosystem for Accreditation in India



Accreditation

A global system for creating confidence between economies with the objective to promote economic growth and free trade

Third-party attestation related to a conformity assessment body conveying **formal demonstration of its competence** to carry out **specific conformity assessment tasks** – **ISO/IEC 17000.**

Conformity Assessment Body is a body that performs conformity assessment activities and that can be the object of accreditation – **ISO/IEC 17000.**

Conformity Assessment activities includes testing, calibration, inspection, certification of management systems, persons, products, processes and services, provision of proficiency testing, production of reference materials, validation and verification – **ISO/IEC 17000.**

Provision for Accreditation in WTO TBT Agreement

"Members shall ensure, whenever possible, that results of conformity assessment procedures in other Members are accepted…adequate and enduring technical competence of the relevant conformity assessment bodies in the exporting Member, so that **confidence in the continued reliability of their conformity assessment results** can exist; in this regard, **verified compliance**, for instance **through accreditation**, with relevant guides or recommendations issued by international standardizing bodies shall be taken into account as an indication of adequate technical competence"

Article 6

NATIONAL ACCREDITATION BOARD FOR CERTIFICATION BODIES

Accredits Certification, Inspection and Validation & Verification Bodies (CBs, IBs & VVBs) as per ISO Standards and other requirements, which are internationally recognized through Mutual Recognition Arrangements of IAF and ILAC

- **Management Systems Certification Bodies**:
  - Quality Management System (QMS)*
  - Energy Management System (EnMS)*
  - Environmental Management System (EMS)*
  - Food Safety Management System (FSMS)*
  - Information Security Management System (ISMS)*
  - Occupational Health and Safety Management System (OHSMS)*
  - Information Technology Service Management Systems (ITSMS)
  - Trustworthy Digital Repositories Management Systems (TDRMS)
  - **Medical Devices Quality Management System (MDQMS)***
- **Product Certification Body***
- **Personnel Certification Body***
- **Inspection Body** (IB)*
- **Green House Gases Validation and Verification Bodies** (GHG VVBs)*

20,000+
Accredited Certificates
through ~100 Accredited CBs

100,000+
Inspection Reports / Certificates
through ~74 Accredited IBs

* MRA/MLA Signatory

MDQMS Scope Sectors

MD SCOPE CLASSIFICATION AS PER IF MD 9:2017		
Main Technical Area (MTA)	**Code**	**Technical Areas (TA)**
Non-active medical devices	A1.1-01	General non-active, non- implantable medical devices
	A1.1-02	Non-active implants
	A1.1-03	Devices for wound care
	A1.1-04	Non-active dental devices and accessories
	A1.1-05	Non-active medical devices other than specified above
Active (Non-Implantable) medical devices	A1.2-01	General active medical devices
	A1.2-02	Devices for imaging
	A1.2-03	Monitoring devices
	A1.2-04	Devices for radiation therapy and thermo therapy
	A1.2-05	Active (non-implantable) medical devices other than specified above
Active Implantable medical devices	A1.3-01	General active implantable medical devices
	A1.3-02	Implantable medical devices other than specified above

MDQMS Scope Sectors

In-Vitro Diagnostic medical devices	A1.4-01	Reagents and reagent products, calibrators and control materials for: a) Clinical Chemistry b) Immunochemistry (Immunology) c) Haematology/Haemostasis/ Immunohematology d) Microbiology e) Infectious Immunology f) Histology/Cytology g) Genetic Testing
	A1.4-02	In Vitro Diagnostic Instruments and software
	A1.4-03	IVD medical devices other than specified above
Sterilization Method for Medical Devices	A1.5-01	Ethylene oxide gas sterilization (EOG)
	A1.5-02	Moist heat
	A1.5-03	Aseptic processing
	A1.5-04	Radiation sterilization (e.g. gamma, x-ray, electron beam)
	A1.5-05	Sterilization method other than specified above

MDQMS Scope Sectors

Devices incorporating / utilizing specific substances / technologies	A1.6-01	Medical devices incorporating medicinal substances
	A1.6-02	Medical devices utilizing tissues of animal origin
	A1.6-03	Medical devices incorporating derivates of human blood
	A1.6-04	Medical devices utilizing micromechanics
	A1.6-05	Medical devices utilizing nanomaterials
	A1.6-06	Medical devices utilizing biological active coatings and/or materials or being wholly or mainly absorbed
	A1.6-07	Medical devices incorporating or utilizing specific substances/technologies/elements, other than specified above
Parts or services	A1.7-01	Raw materials
	A1.7-02	Components
	A1.7-03	Subassemblies
	A1.7-04	Calibration services
	A1.7-05	Distribution services
	A1.7-06	Maintenance services
	A1.7-07	Transportation services
	A1.7-08	Other services

NABL: National Accreditation Board for Testing & Calibration Laboratories

Accredits Testing, Calibration & Medical Laboratories, Reference Material Producers and Proficiency Testing Providers based on International Standards (ISO/IEC 17011)

Testing Laboratories

- Biological
- Chemical
- Electrical
- Electronics
- Fluid-Flow
- Mechanical
- Non-Destructive Testing
- Optical and Photometry
- Radiological
- Thermal
- Forensic

Calibration Laboratories

- Electro-Technical
- Mechanical
- Radiological
- Thermal
- Optical
- Fluid-Flow

RM Producers

Chemical Composition

Biological and Clinical Properties

Physical Properties

Engineering Properties

Medical Laboratories

- Clinical Biochemistry
- Clinical Pathology
- Cytogenetics
- Cytopathology
- Haematology & Immuno-haematology
- Histopathology
- Microbiological & Serology
- Nuclear Medicine (in-vitro)

PT Provider

- Testing
- Calibration
- Medical
- Inspection

6,000+
Accreditations

The International Equivalence in Accreditation

NABCB - Signatory to APAC MRA since 2002, IAF MLA since 2002; APAC & ILAC MRAs for Inspection since 2013

NABL - Signatory to APAC MRA since 2000 for Testing, Calibration & Medical since 2000

Asia Pacific Accreditation Cooperation	International Accreditation Forum	International Laboratory Accreditation Cooperation

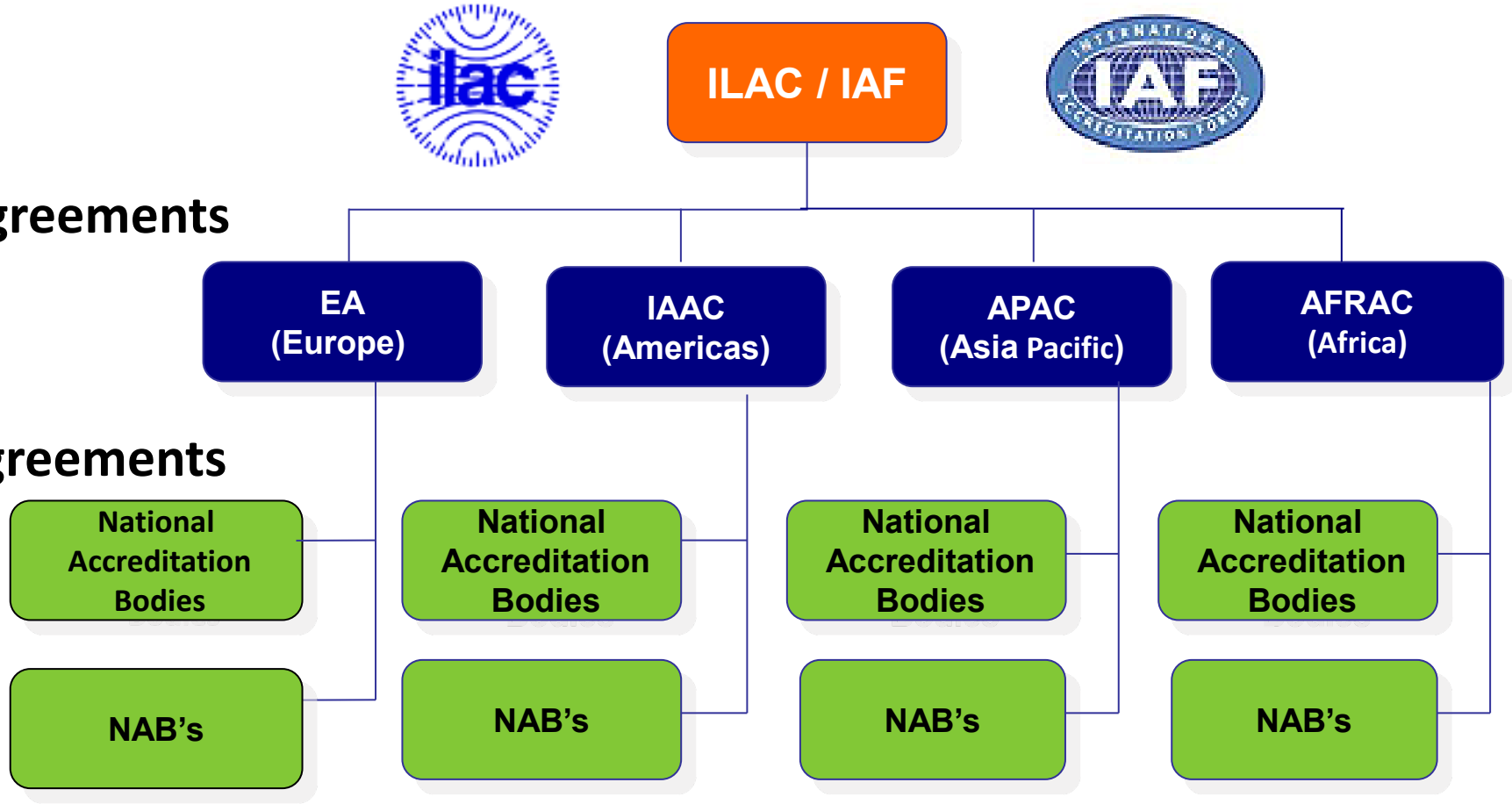
BENEFITS

- **International Equivalence & Acceptance of Accredited Certificates**
- **Assurance of quality**
- **Facilitates Trade**

The International Recognition Framework

International Multilateral Agreements

Regional Multilateral Agreements

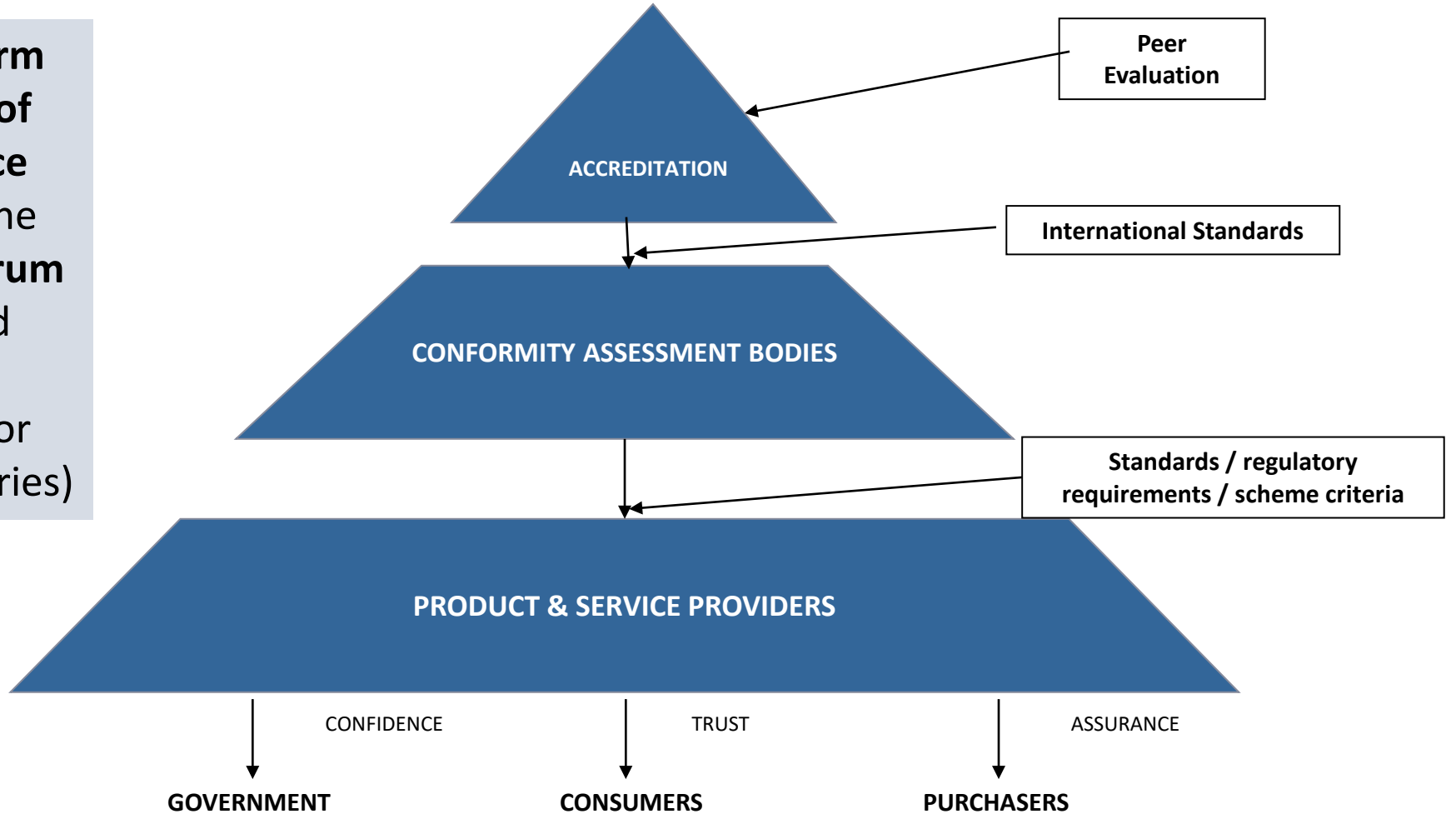


Global Vision

- A single worldwide program of conformity assessment which reduces risk for business, regulators and the consumer, by ensuring that accredited services can be relied upon.
- Government and Regulators relying on the IAF and ILAC Arrangements (MLA / MRA) to further develop or enhance trade agreements.
- To support the freedom of world trade by eliminating technical barriers, realizing the free-trade goal of '***Tested, Inspected or Certified Once and Accepted Everywhere***'

The Accreditation Framework

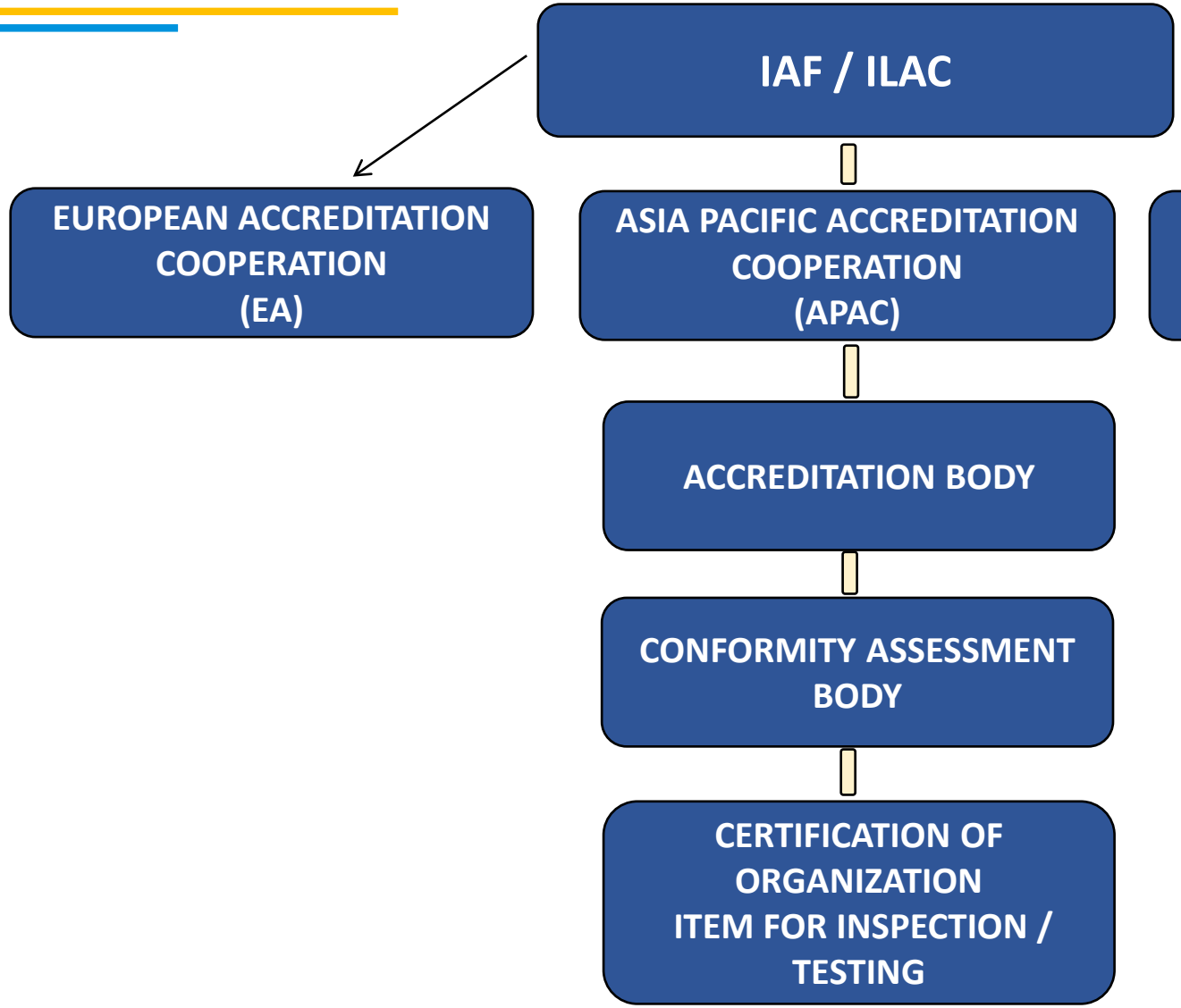
NABCB and NABL together form part of international system of accreditation and equivalence operated under the aegis of the **International Accreditation Forum** (for Certification Bodies) and **International Laboratory Accreditation Cooperation** (for Inspection Bodies and Laboratories)



Accreditation Standards

Standards	Conformity Assessment Bodies
ISO/IEC 17011	Requirements for Accreditation Bodies accrediting Conformity Assessment Bodies
ISO/IEC 17020	Requirements for Inspection Bodies
ISO/IEC 17021-1	Requirements for Management Systems Certification Bodies – ISO 9001, 14001, 22000, 27006 …
ISO 22003	Requirements for Certification Bodies for FSMS – cross refers to ISO 17021
ISO/IEC 17065	Requirements for Certification Bodies Certifying Products, Processes and Services
ISO/IEC 17024	Requirements for Certification Bodies Certifying Personnel
ISO 14065	Requirements for Green House Gases Validation & Verification Bodies
ISO/IEC 17025	Requirements for Testing & Calibration Laboratories
ISO 15189	Requirements for Medical Laboratories
ISO/IEC 17043	Requirements for Proficiency Testing Providers (PTPs)
ISO 17034	Requirements for Reference Material Producers (RMPs)

The Equivalence Framework



ISO/IEC 17011

ISO/IEC 17020
ISO/IEC 17025
ISO/IEC 17021-1
ISO/IEC 17065

Standards against which certified – ISO/IEC Standards, ISO 9001 / ISO 21001 etc.

CDSCO relying on National Accreditation

- National Accreditation Board for Certification Bodies (NABCB) under the Quality Council of India, shall **act as the National Accreditation Body** for the purposes of **accrediting Notified Bodies**.

- NABCB shall be responsible for **carrying out the assessment of Notified Bodies** and issue a certificate in respect of specified categories of standards for which such entity has been assessed and found qualified.

- **Central medical devices testing laboratory** carrying out test and evaluation of medical devices must have **accreditation by the National Accreditation Body for Testing and Calibration Laboratories (NABL)**.

- Laboratories used for **generating data for clinical investigation** should be compliant with Good Laboratory Practices (GLP) or should have **accreditation certificate issued by National Accreditation Board for Testing and Calibration Laboratories (NABL)**.

CDSCO relying on National Accreditation

- The accredited Notified Body shall be **carry out audit of manufacturing sites of Class A and Class B medical devices** to verify conformance with the Quality Management System and other applicable standards as specified under medical device rules.

- Any Notified Body, with an **experience of at least two years**, may apply to the Central Licensing Authority for registration as a Notified Body for **carrying out audit of Class C and Class D medical devices**, provided it has personnel with requisite qualification and experience.

Other Regulators relying on Accreditation

- The **Food Safety and Standards Act, 2006** of India in **section 12(2) prescribes** "that the Food Authority may by regulations specify under (c) the mechanisms and guidelines for **accreditation of certification bodies engaged in certification of food safety management systems** for food businesses". Further, under section 44 on Recognition of organisation or agency for food safety audit, it prescribes "The Food Authority may recognise any organisation or agency for the purposes of food safety audit and checking compliance with food safety management systems required under this Act or the rules and regulations made thereunder."

- The **Food Safety and Standards (Food Safety Auditing) Regulations, 2018** under **section 3(1) prescribes** that the "Food Authority may, for the purpose of carrying out food safety audit, grant recognition to auditing agencies which conform to the following criteria, namely, under (b), it holds a **valid accreditation on ISO/IEC 17020 or ISO/IEC 17021 or ISO/TS 22003 from National Accreditation Board for Certification Bodies** for Management System Certification, for the required food categories specified by the Food Authority."

Other Regulators relying on Accreditation

- **PNGRB** – MoU with QCI in 2008 – accredited Inspection Bodies empaneled for inspections of Gas Pipeline Networks (CGD / NGPL); Review & Onsite Verification of ERDMP

- **DGCA** – Notification for empanelment of NABCB accredited GHG Verification and Validation Bodies for undertaking verification work under Carbon Offsetting and Reduction Scheme for International Aviation (CORSIA) Scheme of International Civil Aviation Organization (ICAO).

- **BEE** - Requires NABCB accredited Product Certification Bodies to carry out activities as Independent Agencies for Monitoring and Evaluation to support implementation of BEE's hugely popular Standards & Labelling (S&L) Programme for star rating of electrical appliances.

List of Accredited CBs under MDQMS

S. No.	Accreditation No.	Name of the Certification Bodies
1	QM009	International Certifications Services Private Ltd.
2	QM011	TUV SUD South Asia Pvt. Ltd.
3	QM033	Intertek India Pvt. Ltd
4	QM010	TUV Rheinland (India) Pvt. Ltd.
5	QM001	DNV GL Business Assurance India Pvt. Ltd.
6	QM002	TUV India Pvt. Ltd.
7	QM030	BSCIC Certifications Pvt. Ltd.
8	QM028	MTIC Intercert India Pvt. Ltd. (Formerly TUV Intercert Saar India Pvt Ltd.)
9	QM062	Zenith Quality Assessors Pvt. Ltd.
10	QM027	SGS India Pvt. Ltd.
11	QM069	ACM EMB Pvt. Ltd.
12	QM070	UL India Pvt. Ltd.
13	QM071	Deutsch Quality Systems (India) Pvt. Ltd.
14	QM006	IRCLASS Systems and Solutions Private Limited

Notified Bodies under CDSCO

- Notified body is competent to carry out the **audit of manufacturing site**, **assessment**, and **verification of specified category of medical devices** for establishing conformity with standards.
- List of Notified Bodies under CDSCO:
  - Intertek India Pvt Ltd.
  - TUV Rheinland India Pvt Ltd.
  - TUV SUD South Asia Pvt Ltd.
  - DNV GL Business Assurance India Private Limited
  - BSCIC CERTIFICATIONS Pvt Ltd.
  - TUV Intercert Saar India Private Limited
  - Zenith Quality Assessors Pvt Ltd.

Benefits of Accreditation

- Assurance of Technical Competence, Reliability and Integrity of Conformity Assessment Bodies
- Demonstrates Compliance to Standards / Regulations / Requirements
- Increased Operational Efficiency, Effective Risk Management, Saves Time & Money
- Facilitates Selection of Suppliers, Promotes Confidence in Imports, Avoids Re-testing/inspection
- Enhances Competitiveness, Marketing Advantage, Increased Business
- Customer Satisfaction, Minimizes Complaints
- International Equivalence/Acceptance/Recognition through Multilateral Mutual Recognition Arrangements

Case studies to demonstrate the value of accredited conformity assessment are available at

https://publicsectorassurance.org/ https://business-benefits.org/

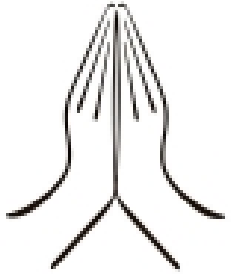
Indian Certification for Medical Devices (ICMED) Scheme

- QCI Voluntary quality certification scheme for medical devices
- Intended to enhance patient safety and provide consumer protection and significantly eliminate trading of sub-standard products/devices of doubtful origins.
- Brings down the substantial time and cost-run to obtain globally accepted quality certification for Indian companies and eliminate the malpractices of sub-standard or fraudulent certification or quality audits.
- Certification under this scheme shall be provided by a NABCB Accredited Certification Body

Levels of Certification:-

- **ICMED 9000 certification** - ISO 9001 plus additional requirements
- **ICMED 13485 certification** - ISO 13485 plus additional requirements
- **ICMED Plus** – Product certification requirements

https://qcin.org/indian-certification-for-medical-devices-icmed-scheme



Thank You !

National Accreditation Board for Certification Bodies

Quality Council of India

2nd Floor, Inst. of Engineers Bldg., 2, Bahadur Shah Zafar Marg,
New Delhi – 110002 | T: +91-11-2337 9321
W: www.qcin.org | E: info@qcin.org; nabcb@qcin.org

www.linkedin.com/company/nabcb

@NABCB_QCI

www.facebook.com/nabcb

Ravi Singh,
Member, TICC, Med Device WG

TIC COUNCIL

THE INDEPENDENT VOICE OF TRUST

Getting Market ready – Role of Third-Party CA/NB's

29 October 2021

Presenter: Ravi Singh, Member TIC Council, Medical Device WG

Contents

Competent Authorities

Belongs to the government of a Member State of the European Union (EU)

Responsible for transposing the requirements of European regulations into national legislation.

An umbrella group “Competent Authorities for Medical Devices (CAMD)” - Responsible for improving communication and collaborative work between competent authorities, and increasing the surveillance of medical devices on the market.

All competent authorities work together in the CAMD network to support patient safety and facilitate the implementation and the enforcement of the regulations on medical devices and in vitro diagnostic devices.

In India – Licensing Authorities are equivalent to Competent Authorities of EU

Notified Bodies

Are independent organizations designated by an EU Member State to make sure that the Medical Device Requirements (MDR) are being followed for as long as the product remains on the market.

Notified Bodies are supervised by the Competent Authority of a particular EU Member State.

Medical devices are initially reviewed and approved by a Notified Body before they are placed on the market.

Notified Bodies are also designated for specific directives, regulations, or products that need higher and stricter safety standards, or that weren't built according to harmonized EN standards, such as medical devices.

Role of Notified Bodies

Evaluation of Correct Classification of Medical

Evaluation of Route chosen by Manufacture to achieve compliance

Evaluation whether correct Harmonised Standards are applied by manufactures

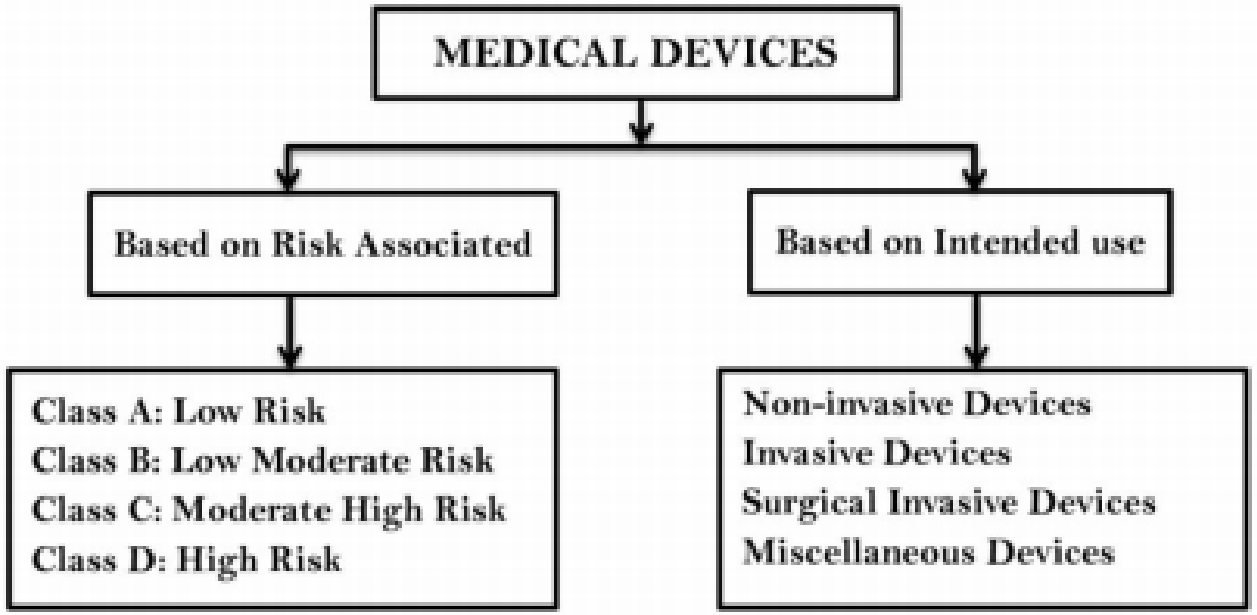
Assessment of Technical Documentation with respect to Essential Requirements set out in Regulation

Quality Management System Audit according to ISO 13485

Production Quality Assurance Audit

Type Examination of medical Devices

Classification of Medical Devices



Routes to Compliance

Example: Class IIb Medical Devices

All Medical Devices		Only Non-Sterile Products	
Route 1	Route 2	Route 1	Route 2
1. Full quality assurance audit by a notified body 2. Creating a Declaration of Conformity 3. Affixing the CE mark and notified body number on the product 4. Placing the medical device on the market	1. Type examination by a notified body 2. Production quality assurance audit by a notified body 3. Creating a Declaration of Conformity 4. Affixing the CE mark and notified body number on the product 5. Placing the medical device on the market	1. Type examination by a notified body 2. A notified body Inspection quality assurance audit (not including design and manufacturing) 3. Declaration of Conformity 4. Affixing the CE mark and notified body number on the product 5. Placing the medical device on the market	1. Type examination by a notified body 2. A notified body needs to verify every device/batch 3. Creating a Declaration of Conformity 4. Affixing the CE mark and notified body number on the product 5. Placing the medical device on the market

How about other Geographies

Routes for compliance for following countries are discussed in next few slides:

Canada

South Africa

Malaysia

Mexico

EEA

India

Canada

I	II	III	IV
Class I devices may skip these steps	Ensure **quality management system (QMS) is implemented (ISO 13485)**		
Apply for Medical Device Establishment License	Apply for Medical Device License (MDL)		
Submit application and pay fee.	Submit application including declaration of conformity (DoC) and **QMS (ISO).** Pay application fee.	**Submit application including DoC, ISO**, and clinical data. Pay application fee.	
Class I devices do not undergo this review process.	Health Canada will review application.	Health Canada will review application. Device will also undergo premarket review.	
If approved, Health Canada will issue registration.			

South Africa

A	B	C	D
Prepare necessary documentation including Conformity Assessment Body (CAB) and Declaration of Conformity (DoC). AR submits application to the Council.	Demonstrate the device meets Essential Principles		
	Demonstrate conformity by applying to a Conformity Assessment Body (CAB) or International Notified Body for the CA certificate.		
	If the application is successful and CA certificate is granted the RA will now prepare Declaration of Conformity (DoC).		
Medical device will be included in the Medical Device register.			

Malaysia

Class A	Class B	Class C	Class D
Ensure products conform to Essential Principle of Safety & Performance (EPSP)			
Exempt from Conformity Assessment Reviews (CAB). Special cases may be audited	**Engage an accredited Conformity Assessment Body (CAB).**		
Complete application on MeDC@St system including: general information, Common Submission Dossier Template (CSDT), Declaration of conformity (DoC), and a certificate of Conformity of the quality management system (QMS) (i) Quality management system (QMS) (ii) System for post-market surveillance (PMS)			
Simplified CSDT	CSDT; (i) Class B/C: clinical evidence, if required (ii) Class C/D: clinical evaluation		
MDA verifies classification and upon approval issues a certificate and assigns a registration number.			

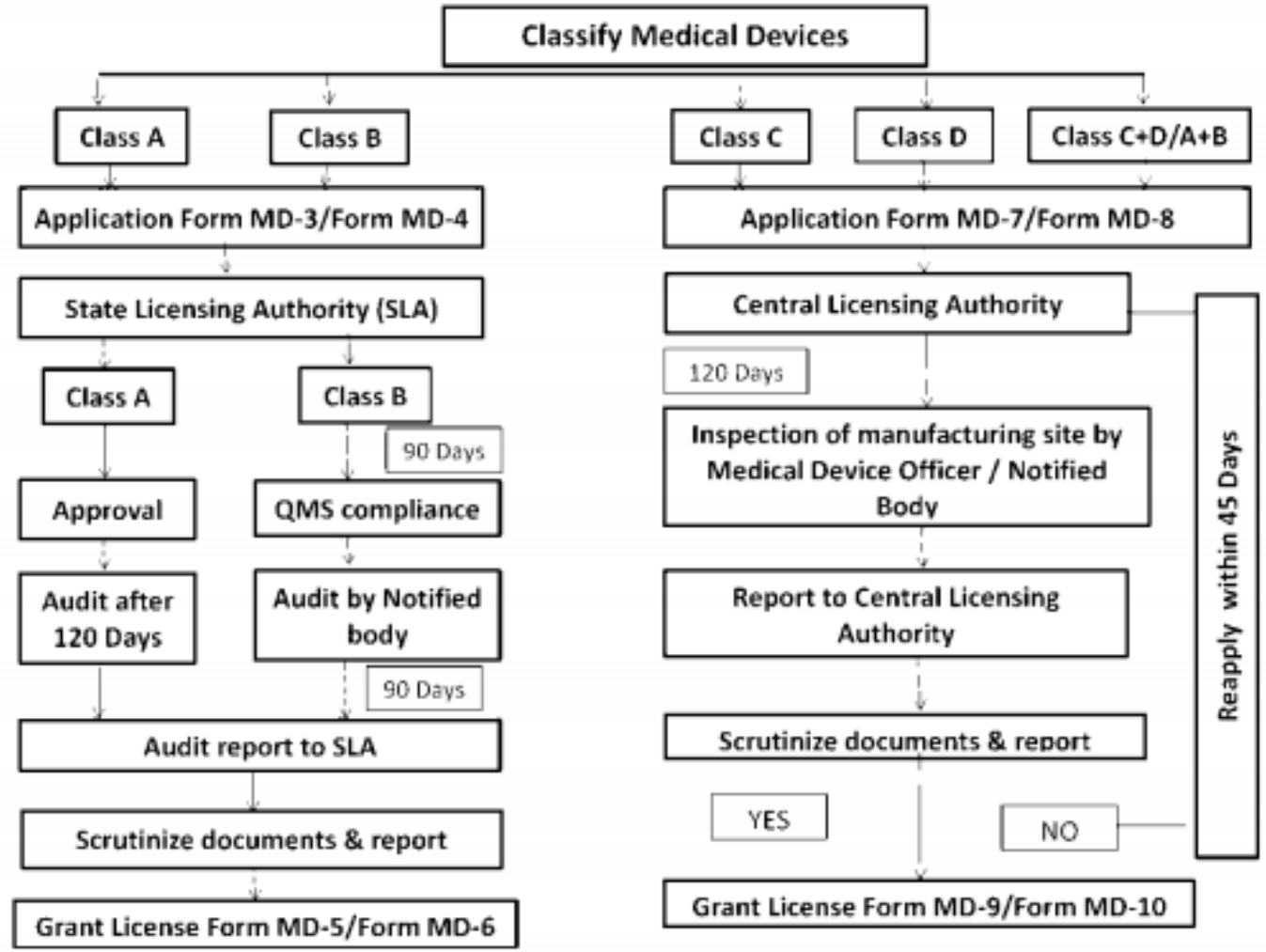
Mexico

Class I Low Risk	Class I	Class II	Class III
Demonstrate home country approval through Certificate of Free Sale (CFS) or Certificate to Foreign Government (CFG).			
Device must comply with ISO 13485 or equivalent in another country . No audit will be performed.			
Must submit basic device information.	Submit registration dossier, which should include safety information, testing reports, clinical trial data. Approval from recognized country (Japan, Canada, or United States) may be leveraged in order to expedite approval.		
if device is approved COFEPRIS will issue certificate and post confirmation of device registration on Ministry of Health website.			

European Economic Area

I (non-sterile, non-measuring)	I (sterile, measuring)	IIa	IIb	III
Quality Management System (QMS) not required.	Implement and provide proof of **QSM (ISO 13485) compliance**.			
Submit technical file with necessary documentation and information.				Submit design dossier
No audit required.	**Application will be audited by Notified Body (NB).**			
N/A	If approved, CE marking will be issued and will be valid for 3 years.			
Prepare and submit Declaration of Conformity (DoC).				
N/A		Some countries within EU require additional registration of Class lla, llb or lll devices.		
If approved, device registration will be granted.				

India


Classify Medical Devices
Class A
Class B
Class C
Class D
Class C+D/A+B
Application Form MD-3/Form MD-4
Application Form MD-7/Form MD-8
State Licensing Authority (SLA)
Central Licensing Authority
Class A
Class B
120 Days
90 Days
Inspection of manufacturing site by Medical Device Officer / Notified Body
Approval
QMS compliance
Audit after 120 Days
Audit by Notified body
Report to Central Licensing Authority
90 Days
Audit report to SLA
Scrutinize documents & report
YES
NO
Reapply within 45 Days
Grant License Form MD-5/Form MD-6
Grant License Form MD-9/Form MD-10

Summary

Competent/Licensing Authorities are entrusted to assure patient safety.

Competent Authorities fulfill their responsibilities through Notified Bodies.

Notified Body works closely with Manufacturers to assess their compliance to regulation.

Almost in all geographies Notified Body play active role in compliance assessment of all category of Medical Devices

In India, use of Notified Bodies for Class C and D medical Devices is at the prerogative of Licensing Authorities.

Notified Bodies have knowledge and Resources to provide more support to Central Licensing Authority of India in Class C and D Medical Devices.

Panel Discussions: Medical Device Industry - Challenges, Solutions & Opportunites

Chair

Girdhar Gyani,
Director General,
AHPI

Moderator

Harshit Thakkar,
Sr. Project Manager,
DEKRA

Panel Discussions: Medical Device Industry - Challenges, Solutions & Opportunites

Speakers

Sudhakar Mairpadi
Head Quality, Regulatory and Govt Affairs, Philips India Pvt Ltd

Rajiv Nath
Forum Coordinator, AiMED

Vibhav Garg
Director
Health Economics & Govt Affairs, Boston Scientific

R. Asok Kumar
Chairman, Regulatory Sub Committee, Adva Med

Questions?

Way Forward and Wrap Up

Dr. Aparna Dhawan,
Executive Director,
TIC Council, India

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