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
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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
Accreditation: Supports Implementation of Medical Devices Regulations

National Accreditation Board for Certification Bodies (NABCB)
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 **CAGR 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.
Manufacturing Clusters for Medical Devices

- **Gujarat**: Pharmaceuticals, Ahmedabad, Vapi Industrial Corridors
- **Maharashtra**: Pharmaceuticals, Mumbai, Pune, Nagpur
- **Karnataka**: Insulin Pens, Stents & Implants, Medical Electronics, Bengaluru, Mangalore
- **Haryana**: Low-End Medical Consumables, Chandigarh, Ballabgarh, Faridabad, Manesar
- **Andhra Pradesh, Telangana**: Medical Electronics, Hyderabad, AMTZ Medtech Park in Visakhapatnam; Sultanpur (Upcoming in Telangana)
- **Tamil Nadu**: Medical Electronics, HLL Medipark, Chennai

[Source: 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.

**High Risk**
Coronary stents, cardiac catheterization kits, cardiovascular, intravascular diagnostic catheters etc.

**Low Moderate Risk**
Endoscopic forceps, vial adapters, suction cups and catheters, feeding tubes etc.

**Moderate High Risk**
Anesthesia conduction filter, introducer sheath, microcatheter, imaging catheter, colonic stents, pancreatic instruments etc.
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

ACCREDITATION
- ISO/IEC 17021
- ISO/IEC 17065

CERTIFICATION
- product certification
- CE etc.

STANDARDIZATION
- national/international standards

TESTING | INSPECTION
- testing, analysis, research inspection
- calibration of equipment, reference materials, verification

METROLOGY
- traceability recognition

Applicable to all products, processes and services

ISO 9000/14000
HACCP etc.

International System

National value chains

www.nabcb.qci.org.in
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)***

* MRA/MLA Signatory

20,000+ Accredited Certificates through ~100 Accredited CBs

100,000+ Inspection Reports / Certificates through ~74 Accredited IBs
<table>
<thead>
<tr>
<th>Main Technical Area (MTA)</th>
<th>Code</th>
<th>Technical Areas (TA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-active medical devices</td>
<td></td>
<td></td>
</tr>
<tr>
<td>A1.1-01</td>
<td>General non-active, non-implantable medical devices</td>
<td></td>
</tr>
<tr>
<td>A1.1-02</td>
<td>Non-active implants</td>
<td></td>
</tr>
<tr>
<td>A1.1-03</td>
<td>Devices for wound care</td>
<td></td>
</tr>
<tr>
<td>A1.1-04</td>
<td>Non-active dental devices and accessories</td>
<td></td>
</tr>
<tr>
<td>A1.1-05</td>
<td>Non-active medical devices other than specified above</td>
<td></td>
</tr>
<tr>
<td>Active (Non-Implantable) medical devices</td>
<td></td>
<td></td>
</tr>
<tr>
<td>A1.2-01</td>
<td>General active medical devices</td>
<td></td>
</tr>
<tr>
<td>A1.2-02</td>
<td>Devices for imaging</td>
<td></td>
</tr>
<tr>
<td>A1.2-03</td>
<td>Monitoring devices</td>
<td></td>
</tr>
<tr>
<td>A1.2-04</td>
<td>Devices for radiation therapy and thermo therapy</td>
<td></td>
</tr>
<tr>
<td>A1.2-05</td>
<td>Active (non-implantable) medical devices other than specified above</td>
<td></td>
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<tr>
<td>Active Implantable medical devices</td>
<td></td>
<td></td>
</tr>
<tr>
<td>A1.3-01</td>
<td>General active implantable medical devices</td>
<td></td>
</tr>
<tr>
<td>A1.3-02</td>
<td>Implantable medical devices other than specified above</td>
<td></td>
</tr>
</tbody>
</table>
### MDQMS Scope Sectors

#### In-Vitro Diagnostic medical devices

<table>
<thead>
<tr>
<th>A1.4-01</th>
<th>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</th>
</tr>
</thead>
<tbody>
<tr>
<td>A1.4-02</td>
<td>In Vitro Diagnostic Instruments and software</td>
</tr>
<tr>
<td>A1.4-03</td>
<td>IVD medical devices other than specified above</td>
</tr>
</tbody>
</table>

#### Sterilization Method for Medical Devices

<table>
<thead>
<tr>
<th>A1.5-01</th>
<th>Ethylene oxide gas sterilization (EOG)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A1.5-02</td>
<td>Moist heat</td>
</tr>
<tr>
<td>A1.5-03</td>
<td>Aseptic processing</td>
</tr>
<tr>
<td>A1.5-04</td>
<td>Radiation sterilization (e.g. gamma, x-ray, electron beam)</td>
</tr>
<tr>
<td>A1.5-05</td>
<td>Sterilization method other than specified above</td>
</tr>
</tbody>
</table>
# MDQMS Scope Sectors

## Devices incorporating / utilizing specific substances / technologies

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A1.6-01</td>
<td>Medical devices incorporating medicinal substances</td>
</tr>
<tr>
<td>A1.6-02</td>
<td>Medical devices utilizing tissues of animal origin</td>
</tr>
<tr>
<td>A1.6-03</td>
<td>Medical devices incorporating derivates of human blood</td>
</tr>
<tr>
<td>A1.6-04</td>
<td>Medical devices utilizing micromechanics</td>
</tr>
<tr>
<td>A1.6-05</td>
<td>Medical devices utilizing nanomaterials</td>
</tr>
<tr>
<td>A1.6-06</td>
<td>Medical devices utilizing biological active coatings and/or materials or being wholly or mainly absorbed</td>
</tr>
<tr>
<td>A1.6-07</td>
<td>Medical devices incorporating or utilizing specific substances/technologies/elements, other than specified above</td>
</tr>
</tbody>
</table>

## Parts or services

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A1.7-01</td>
<td>Raw materials</td>
</tr>
<tr>
<td>A1.7-02</td>
<td>Components</td>
</tr>
<tr>
<td>A1.7-03</td>
<td>Subassemblies</td>
</tr>
<tr>
<td>A1.7-04</td>
<td>Calibration services</td>
</tr>
<tr>
<td>A1.7-05</td>
<td>Distribution services</td>
</tr>
<tr>
<td>A1.7-06</td>
<td>Maintenance services</td>
</tr>
<tr>
<td>A1.7-07</td>
<td>Transportation services</td>
</tr>
<tr>
<td>A1.7-08</td>
<td>Other services</td>
</tr>
</tbody>
</table>
NABL: National Accreditation Board for Testing & Calibration Laboratories


**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

**Medical Laboratories**
- Clinical Biochemistry
- Clinical Pathology
- Cytogenetics
- Cytopathology
- Haematology & Immunohaematology
- Histopathology
- Microbiological & Serology
- Nuclear Medicine (in-vitro)

**PT Provider**
- Testing
- Calibration
- Medical
- Inspection

**RM Producers**
- Chemical Composition
- Biological and Clinical Properties
- Physical Properties
- Engineering Properties

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

BENEFITS

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

www.nabcb.qci.org.in
The International Recognition Framework

International Multilateral Agreements

Regional Multilateral Agreements

EA (Europe)  
National Accreditation Bodies  
NAB’s

IAAC (Americas)  
National Accreditation Bodies  
NAB’s

APAC (Asia Pacific)  
National Accreditation Bodies  
NAB’s

AFRAC (Africa)  
National Accreditation Bodies  
NAB’s

ILAC / IAF
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

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

- IAF / ILAC
  - EUROPEAN ACCREDITATION COOPERATION (EA)
  - ASIA PACIFIC ACCREDITATION COOPERATION (APAC)
  - INTER AMERICAN ACCREDITATION COOPERATION (IAAC)

- ACCREDITATION BODY
- CONFORMITY ASSESSMENT BODY
- CERTIFICATION OF ORGANIZATION ITEM FOR INSPECTION / TESTING

Standards against which certified:
- ISO/IEC 17011
- ISO/IEC 17020
- ISO/IEC 17025
- ISO/IEC 17021-1
- ISO/IEC 17065

- 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

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Accreditation No.</th>
<th>Name of the Certification Bodies</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>QM009</td>
<td>International Certifications Services Private Ltd.</td>
</tr>
<tr>
<td>2</td>
<td>QM011</td>
<td>TUV SUD South Asia Pvt. Ltd.</td>
</tr>
<tr>
<td>3</td>
<td>QM033</td>
<td>Intertek India Pvt. Ltd</td>
</tr>
<tr>
<td>4</td>
<td>QM010</td>
<td>TUV Rheinland (India) Pvt. Ltd.</td>
</tr>
<tr>
<td>5</td>
<td>QM001</td>
<td>DNV GL Business Assurance India Pvt. Ltd.</td>
</tr>
<tr>
<td>6</td>
<td>QM002</td>
<td>TUV India Pvt. Ltd.</td>
</tr>
<tr>
<td>7</td>
<td>QM030</td>
<td>BSCIC Certifications Pvt. Ltd.</td>
</tr>
<tr>
<td>8</td>
<td>QM028</td>
<td>MTIC Intercert India Pvt. Ltd. (Formerly TUV Intercert Saar India Pvt Ltd.)</td>
</tr>
<tr>
<td>9</td>
<td>QM062</td>
<td>Zenith Quality Assessors Pvt. Ltd.</td>
</tr>
<tr>
<td>10</td>
<td>QM027</td>
<td>SGS India Pvt. Ltd.</td>
</tr>
<tr>
<td>11</td>
<td>QM069</td>
<td>ACM EMB Pvt. Ltd.</td>
</tr>
<tr>
<td>12</td>
<td>QM070</td>
<td>UL India Pvt. Ltd.</td>
</tr>
<tr>
<td>13</td>
<td>QM071</td>
<td>Deutsch Quality Systems (India) Pvt. Ltd.</td>
</tr>
<tr>
<td>14</td>
<td>QM006</td>
<td>IRCLASS Systems and Solutions Private Limited</td>
</tr>
</tbody>
</table>
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://publicsectorassurance.org/)
- [https://business-benefits.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](https://qcin.org/indian-certification-for-medical-devices-icmed-scheme)
Thank You!

National Accreditation Board for Certification Bodies
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@NABC_QCI
www.facebook.com/nabcb
Ravi Singh,
Member, TICC, Med Device WG
Getting Market ready – Role of Third-Party CA/NB’s
29 October 2021
Presenter: Ravi Singh, Member TIC Council, Medical Device WG
Contents

Role of Competent Authorities (CAs)

Role of Notified Bodies (NBs)

Some Examples of other Geographies

India MDR 2017 - Role of Licensing Authorities and Notified Bodies
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

MEDICAL DEVICES

Based on Risk Associated
- Class A: Low Risk
- Class B: Low Moderate Risk
- Class C: Moderate High Risk
- Class D: High Risk

Based on Intended use
- Non-invasive Devices
- Invasive Devices
- Surgical Invasive Devices
- Miscellaneous Devices
# Routes to Compliance

## Example: Class IIb Medical Devices

<table>
<thead>
<tr>
<th>All Medical Devices</th>
<th>Only Non-Sterile Products</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Route 1</strong></td>
<td><strong>Route 2</strong></td>
</tr>
<tr>
<td>1. Full quality assurance audit by a notified body</td>
<td>1. Type examination by a notified body</td>
</tr>
<tr>
<td>2. Creating a Declaration of Conformity</td>
<td>2. Production quality assurance audit by a notified body</td>
</tr>
<tr>
<td>3. Affixing the CE mark and notified body number on the product</td>
<td>3. Creating a Declaration of Conformity</td>
</tr>
<tr>
<td>4. Placing the medical device on the market</td>
<td>4. Affixing the CE mark and notified body number on the product</td>
</tr>
<tr>
<td>5. Placing the medical device on the market</td>
<td>5. Placing the medical device on the market</td>
</tr>
</tbody>
</table>
How about other Geographies

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

Canada
South Africa
Malaysia
Mexico
EEA
India
### Canada

<table>
<thead>
<tr>
<th>I</th>
<th>II</th>
<th>III</th>
<th>IV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class I devices may skip these steps</td>
<td>Ensure <strong>quality management system (QMS) is implemented (ISO 13485)</strong></td>
<td>Apply for Medical Device Establishment License</td>
<td>Apply for Medical Device License (MDL)</td>
</tr>
<tr>
<td>Apply for Medical Device Establishment License</td>
<td>Submit application including declaration of conformity (DoC) and <strong>QMS (ISO)</strong>. Pay application fee.</td>
<td>Submit application including DoC, ISO, and clinical data. Pay application fee.</td>
<td></td>
</tr>
<tr>
<td>Submit application and pay fee.</td>
<td>Health Canada will review application.</td>
<td>Health Canada will review application. Device will also undergo premarket review.</td>
<td></td>
</tr>
<tr>
<td>Class I devices do not undergo this review process.</td>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>

If approved, Health Canada will issue registration.
### South Africa

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

Medical device will be included in the Medical Device register.
<table>
<thead>
<tr>
<th>Class A</th>
<th>Class B</th>
<th>Class C</th>
<th>Class D</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ensure products conform to Essential Principle of Safety &amp; Performance (EPSP)</td>
<td>Exempt from Conformity Assessment Reviews (CAB). Special cases may be audited</td>
<td><strong>Engage an accredited Conformity Assessment Body (CAB).</strong></td>
<td></td>
</tr>
<tr>
<td>Complete application on <a href="#">MeDC@St system</a> including: general information, Common Submission Dossier Template (<a href="#">CSDT</a>), 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)</td>
<td>Simplified CSDT</td>
<td>CSDT; (i) Class B/C: clinical evidence, if required (ii) Class C/D: clinical evaluation</td>
<td></td>
</tr>
<tr>
<td>MDA verifies classification and upon approval issues a certificate and assigns a registration number.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**Mexico**

<table>
<thead>
<tr>
<th>Class I Low Risk</th>
<th>Class I</th>
<th>Class II</th>
<th>Class III</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Demonstrate home country approval through Certificate of Free Sale (CFS) or Certificate to Foreign Government (CFG).</strong></td>
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</tr>
</tbody>
</table>

**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

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

Chair
Girdhar Gyani, Director General, AHPI

Moderator
Harshit Thakkar, Sr. Project Manager, DEKRA
Panel Discussions: Medical Device Industry - Challenges, Solutions & Opportunities

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
Way Forward and Wrap Up

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