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Impact of Changes to India under The European Medical Device Regulation (MDR) ((EU) 2017/745) and In Vitro Device Regulation (IVDR) ((EU) 2017/746)

An APACMed India Position Paper on EU MDR & IVDR

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Contents

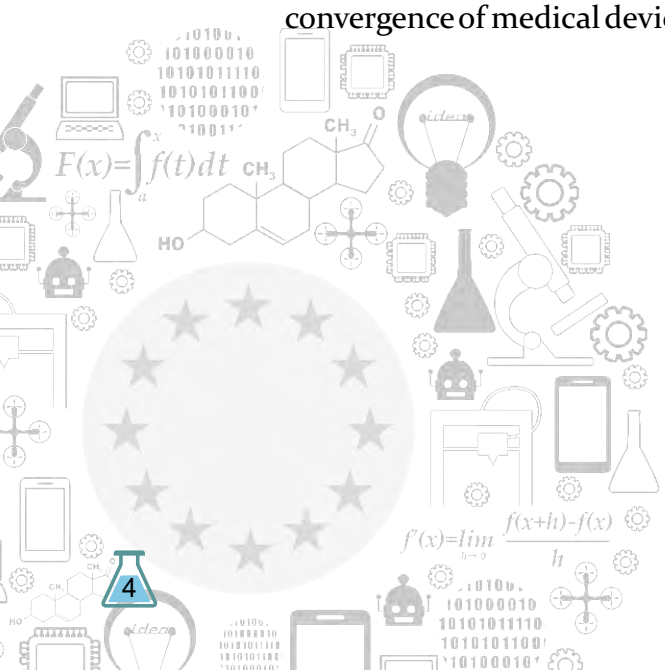
1 Introduction

The European Medical Device Regulation (MDR) ((EU) 2017/745) and In Vitro Device Regulation (IVDR) ((EU) 2017/746) are applicable from 26 May 2021 and 26 May 2022, respectively. It introduces a major update to the regulatory framework in the European Union and will replace the existing In-Vitro Diagnostic Medical Devices Directive (98/79/EC)(IVDD) whereas the MDR replaces the Medical Devices Directive (MDD) (93/42/EEC) and Active Implantable Medical Devices Directive (AIMDD) (90/385/EEC).

The new Regulations create a robust, transparent, and sustainable regulatory framework, recognized internationally, that improves clinical safety and creates fair market access for manufacturers. In contrast to Directives, Regulations are directly applicable and do not need to be transposed into national law. The MDR and the IVDR will therefore reduce the risks of discrepancies in interpretation across the EU market.

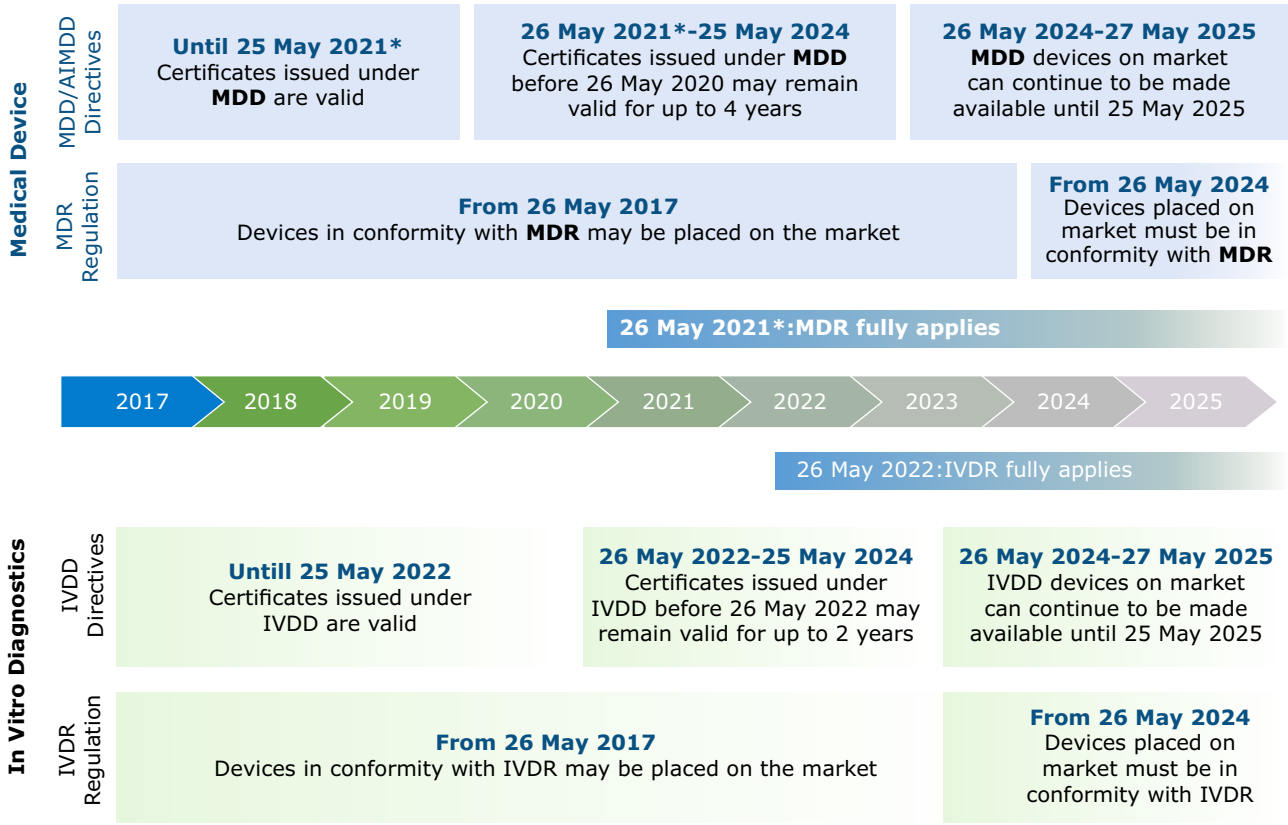
2 Drivers for Change

- **EU laws** on Medical Devices and In -Vitro Diagnostics (IVDs) were over **20 years old**
- **Needing adaptation to technical/scientific progress**
- Device/Drug combinations
- Companion diagnostics - an in vitro device, which provides information that is essential for the safe and effective use of a corresponding drug or biological product
- Move from hospital to home setting
- **Digitalization:** E-Health and M-Health
    - **E-Health:** Healthcare practice supported by electronic communication (e.g., electronic patient record, tele medicine) (Wikipedia)
    - **M-Health:** Mobile health, practice of medicine and public health supported by mobile device. The term is most commonly used in reference to using mobile communication devices, such as mobile phones, tablet computers and PDAs, and wearable devices such as smart watches, for health services, information, and data collection (Wikipedia)
    - **Globalization:** To aid globalization of the medical device market, and to quickly provide innovative medical devices to patients, to encourage harmonization and convergence of medical device regulations



3 Transition Period

Figure 1: EU MDR/IVDR Transition timeline for EU markets



*Extended by 1 year from May 2020 to May 2021 due to COVID-19 impact

4 Changes from Existing Directives

- Risk classification of IVD
- As per IVDD approx. 80% of IVDs are self-certified and 20% through notified body and As per IVDR 20% of IVDs are self - certified and 80% are certified through notified body
- Clarification of obligations of economic operators
  (Manufacturers, authorized representatives, importers and distributors)
- Robust Post-Market Surveillance and Vigilance
- Role of Notified Bodies
- Tightened requirements for clinical evidence and conformity assessment
- Introduction of a unique device identifier (UDI) for every IVD & Medical Devices
- Registration of the medical device, the Notified Body certification documents, and economic operators in the European Database (EUDAMED– European Databank on Medical Devices) to increase transparency
- Increased transparency, with information on IVD devices and 'higher risk' performance studies being made public in the new European Database for Medical Devices (EUDAMED)

5 Assessment of Changes on Product's Risk, Quality, & Performance of IVD & Medical Devices

Type of Information	Type of Changes	Does the change impact risk / benefit of the device	Does it change use of the device	Does it affect Product quality & performance
Labels	Additional information, including UDI, notified body number, new symbols (self- test, near-patient testing, single use), etc.	No	No	No
IFU	Additional information, including notified body number, clarification for changes (intended use, specified in available performance data)	No	No	No
Notified Body Certificates (NB)	Additional information UDI, notified body number, product Certificates classification, etc.	No	No	No
Declaration of Conformity (DOC)	Additional information, including UDI, notified body number, product classification, registration number of manufacturer and of European authorized representative	No	No	No
Classification	IVDR adopts new IVD classification based on IMDRF classification (class A, B, C, D) which will be reported on CE certificates and CE Declarations of Conformity	No	No	No
Free Sales Certificate	Additional information, including Basic UDI, notified body certificate Sale (FSC) number. Possible new layout for the FSC as IVDR foresees the possibility to adopt a model format.	No	No	No

6 What it Means to India: Assessment of EU-MDR/IVDR Changes and Impact to India

The new regulations for (EU) 2017/745 (MDR) and 2017/746/EU (IVDR) are applicable from 26 May 2021 and 26 May 2022 respectively depending on the risk classification. The documentation requirements for product labels and instructions for use will be updated under the new regulations.

While companies in India are not directly impacted by the EU regulations, however, we are indirectly impacted by the changes made to the global products. Changes in documentation triggered byMDR/IVDR are being gradually implemented and will continue until May 2025.

These changes vary from product to product and **not all changes will apply to all devices**. Most changes will result in additional information being added to labels/IFU, but this **does not change the safety, quality and efficacy of the registered devices.**

The regulatory framework in INDIA is governed by MDR 2017 rules and as per Sixth schedule [rules 26(iii), 26(iv), 38(v) and 38(vii)] of MDR, every change post approval has to be notified to CDSCO. Minor Change as per Rule 26(iv) and Rule 38 (Vii) requires only notification whereas major changes as per rules 26(iii), & 38(v) requires approval from CDSCO.

7 Recommendation & Proposal To CDSCO

The following sections of this position paper illustrates the categories of IVDR triggered changes as well as our proposal to CDSCO.

Proposed Categories	Category 1 Addition of purely administrative generic information	Category 2 Category 1 + clarification of product information	Category 3 Category 1 + change of intended purpose and / or add new patient or user information
Changes to Label	CE-Notified body number	CE-Notified body number	CE-Notified body number number
Changes to Pack Inserts/ Instruction for use (IFU)	• Clear user description • Environmental and biological waste warning • Summary of Safety and • Performance Report (SSP) link • Contact Number • UDI	• Clear user description • Environmental and biological waste warning • Summary of Safety and • Performance Report (SSP) link • Contact Number • UDI	• Clear user description • Environmental and biological waste warning • Summary of Safety and • Performance Report (SSP) link • Contact Number • UDI
	--------	+	+
		• Clarification (not change) of intended purpose • Addition and/or clarification of existing available performance data	• Intended purpose change and/or • New performance data (from studies and/ or literature)
Patient or User Risk	None	None	According to the new intended purpose/claims

Proposed Categories	Category 1 Addition of purely administrative generic information	Category 2 Category 1 + clarification of product information	Category 3 Category 1 + change of intended purpose and / or add new patient or user information
Percentage	**Majority**	Small part	Few
Proposal	**A. Allow exemption in line with best practices in major regulatory agencies.** e.g. HSA Singapore has exempted the requirement to notify such changes as there is no change in technical data Or B. Minor change notification	As per schedule VI of change approval process of MDR 2017 - Minor post approval change requirements	As per schedule VI of change approval process of MDR 2017 -Major post approval change requirements.
Rational	• No Change in Technical Data	• No Change in Intended uses.	• Addition of New performance Data

8 Requirements/Additional Proposals for IVDR & MDR Change Applications

- **Separate Tab for IVDR & MDR Change Submissions** - In present online portal, there are separate tabs for label changes, IFU changes, Intended uses update etc., For IVDR & MDR changes, an applicant have to make multiple change application for same product that will unnecessarily complicate and delay the approval of notifications. Hence, a separate IVDR & MDR Tab for notifying Changes need to be incorporated in the Sugam portal.

- Changes already approved under current system to remain valid and there would not be any need to re-submit those changes.

- **Risk Class** – EU-IVDD directives were following list-based approach and were not having risk-based classification systems, which has now been implemented for IVDR products. Risk Classification in India is governed by Part II of the First Schedule, of MDR-2017, so variation in risk class of any product having lower risk and higher risk as per CDSCO, must not require any notification. Whereas products, which are now, classified as higher risk as per EU IVDR/MDR compared to CDSCO risk class-should require only notification via new-IVDR/MDR tab in Sugam system. Since the risk classification of any devices in India are guided by MDR-2017, change in risk classification of product due to IVDR/MDR must not require a major change approval process or any additional fees unless CDSCO releases new classification list, else this will also impact the locally manufactured products.

- **FSC** - Free Sales Certificate, issued with the corresponding certificates under both IVDD/MDD and the IVDR/MDR will be equally valid during the transition period.

- In case of discontinuation of CE mark in EU market, Import of Non-CE product must not prohibit to import to India if applicant submits the Regulatory Approval from any of the GHTF Country if there is no change in the Intended for Use of already approved Device.

- **Hard Stop/Cut Off**-Approval from CDSCO of IVDR & MDR Changes must not prohibit applicants from importing older IVDD/MDD stock. The production of IVDR & MDR ready lots will take additional time from the date CE-IVDR/MDR certificates are signed. Additionally, some IVDD/MDD devices with certificates issued under the directives may continue to be placed on the EU market until 27 May 2024 and made available until 25 May 2025. Hence IVDD & MDD stocks should be allowed until the implementation timeline suggested by applicant in their change application.

About The Asia Pacific Medical Technology Association (APACMed)

Founded in 2014, the Asia Pacific Medical Technology Association (APACMed) is the only regional association to provide a unified voice for the medical technology industry in Asia Pacific, representing both multinational corporations as well as small and medium enterprises, together with several local industry associations across the region. Headquartered in Singapore, APACMed's mission is patient-centric, and we strive to continuously improve the standards of care for patients through innovative collaborations among stakeholders to jointly shape the future of healthcare in Asia Pacific. We are committed to working with governments and other stakeholders to facilitate patient access to innovative and life-saving medical technologies, supporting strong and thriving healthcare systems across the region, and promoting a robust and sustainable regional ecosystem that encourages investment, trade and innovation.

Key Contributors to the Paper

Regional Team: Yasha Huang (Roche), Joyce Tan (BD), Debra Anne Anthony Peter (Qiagen), Martini Hoan (Thermo Fisher), Jacqueline Monteiro (Abbott), Adelheid Schneider (Roche)

India Team: Rajat Saxena (Siemens Healthineers), Sushant Jaiswal (Roche), Bivash Chakraborty (Biomerieux), Gaurav Verma (BD), Kirti Arora (Boston Scientific), Asok Raghavan Nair (Abbott), Latika Vats (Medtronic)

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Contact APACMed India

Anirudh Sen
Country Lead India & Director Regulatory Affairs APAC
anirudh_sen@apacmed.org
+91 9810170348

Ankit Sharma
Manager, APACMed India
ankit_sharma@apacmed.org
+91 9810307528

1st Floor, Tower B, Unitech Business Park, Block F, South City I, Sector 41
Gurugram, 1220002, Haryana, India

Asia Pacific Medical Technology Association (APACMed)2 Science Park Drive, Ascent
Tower A, #02-07, Science Park I, S118222, Singapore