January 26, 2018

# New EU MDR Regulations and Revamp of the Medical Device Directive

By Shilpa Gampa

An overview of the key impact points and challenges of European Union Medical Device Regulation.

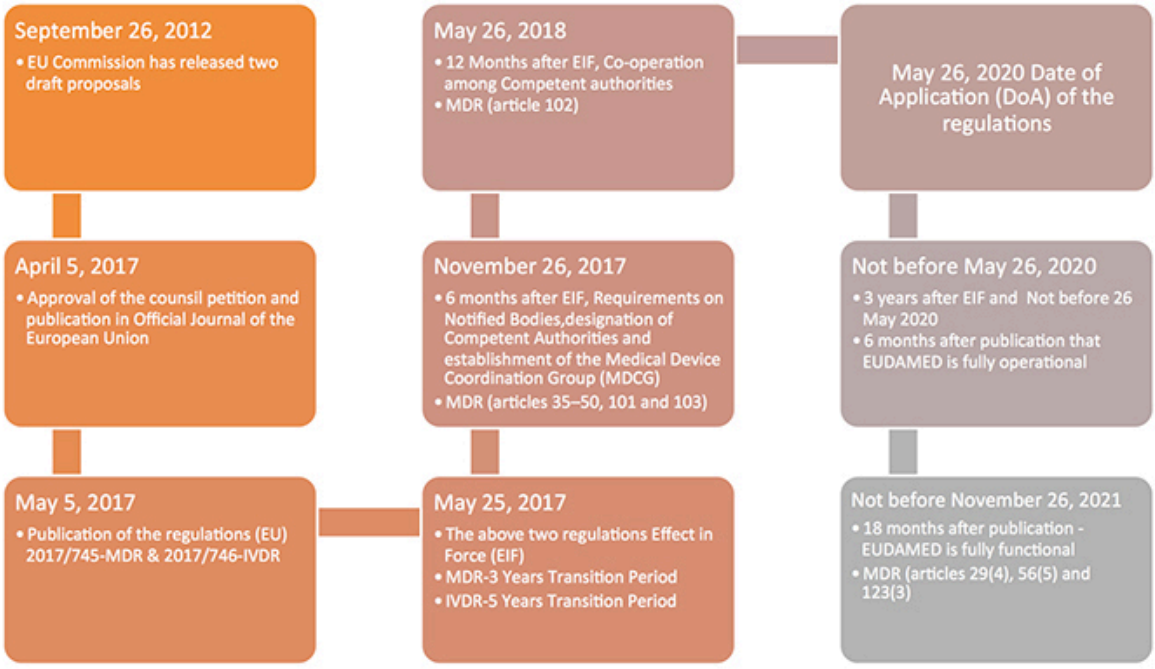
The new Europe (EU) Medical Device Regulations (MDR) published by the European Commission on May 5, 2017 revamped major portions of the EU Medical Device Directive (MDD), raising compliance bars for all device manufacturers, economic operators and notified bodies. The new regulations show a way forward towards the globalization of medical device regulations, which contribute to a high level of safety and facilitate easy trade across the borders by the introduction of unique device identification(UDI), general safety and performance requirements, technical documentation, classification rules, conformity assessment procedures and clinical investigations.

The term 'medical device' encompasses a variety of products, ranging from simple thermometers to artificial intelligence software programs for diagnosing diseases using patient test report data. Development of new products to meet user needs is progressing unimaginably with the advent of digitization and rapid evolution in medical and scientific innovation. Yet with the advent of serious cases involving devices such as the PIP breast implant scandal, there is a need for more stringent regulations.

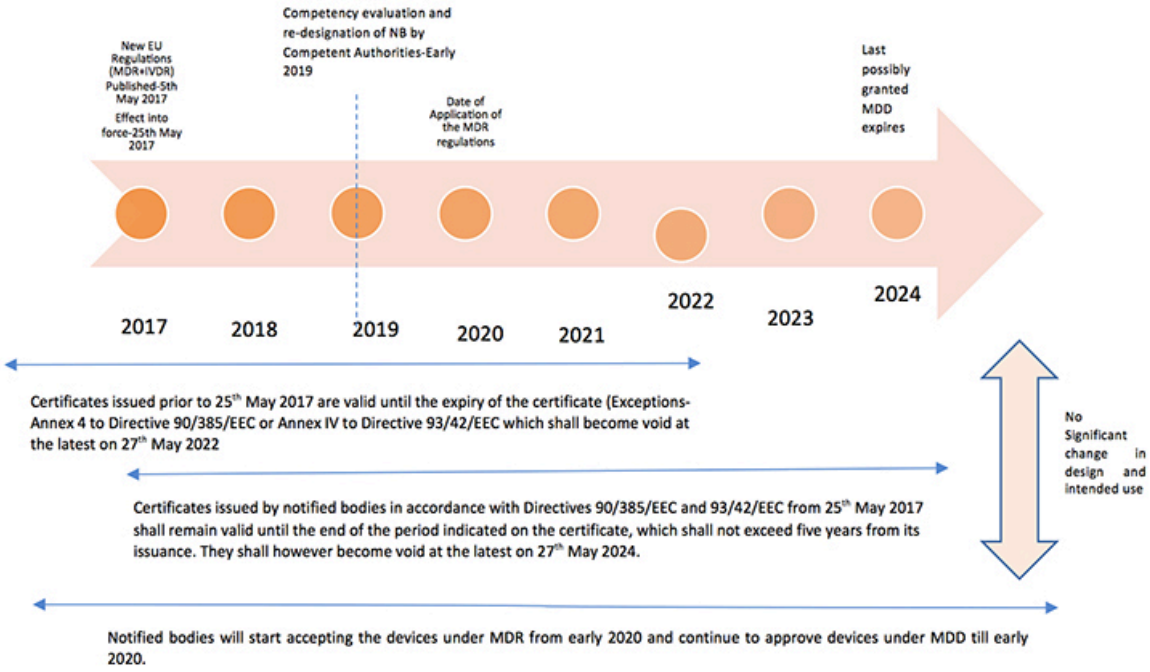
**Overview**

> *"The current Regulatory approach which includes supervision of notified bodies, conformity assessment procedures, clinical investigations and clinical evaluation, vigilance and market surveillance should be reinforced to strengthen further. Also, more provisions should be introduced to ensure transparency and traceability regarding medical devices, to improve health and safety." –Regulation 2017/745*

| Medical Device Directive | Medical Device Regulations |
|---|---|
| 90/385/EEC (AIMD)-20 pages | Regulation EU 2017/745-177 pages<br>Repealing Council Directives 90/385/EEC and 93/42/ EEC (MDD+AIMD) |
| 23 Articles, XVII Annexes | 123 Articles, XVII Annexes |
| Total number of rules for<br><br>classification: 18 | Total number of rules for classification: 22 |




Chronology of Events: Adoption




Chronology of Events: Adoption

**Understanding the MDR**

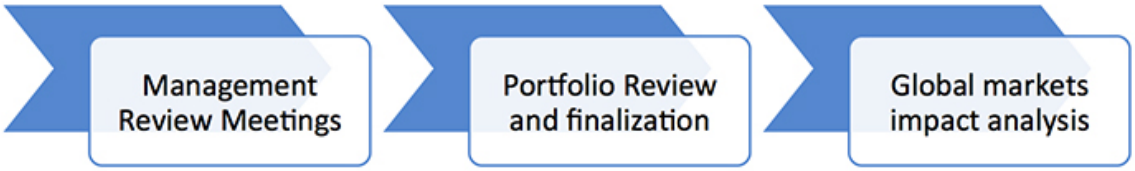
**1. Consider the classification of your device; finalization of your product portfolio**

If your device is currently an accessory to a medical device, a product with aesthetic or another non-medical purpose, is a borderline product containing medicinal substances, or is

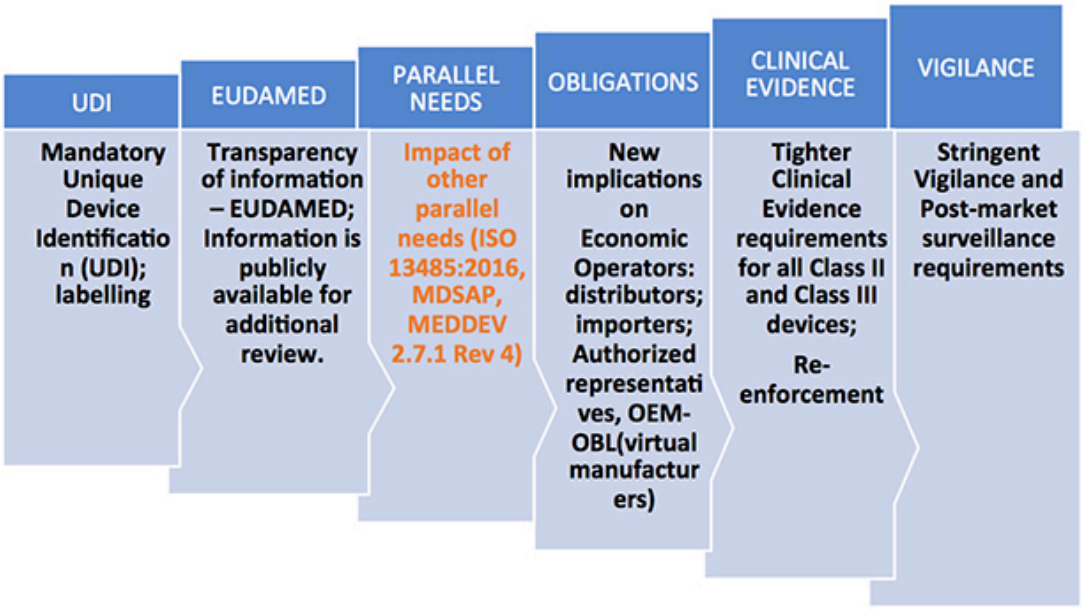
a combination product, or software product, then the new medical device regulations should be evaluated for the classification and up-classification of the device.

The classification and up-classification of devices has a major impact on manufacturers, as EU MDR imposes tighter compliance, safety and efficacy requirements. This will play a key role in finalizing current and future product portfolios due to the significant cost of compliance. Any changes should start at the management level and include key decision makers who determine the product portfolio for the European market, assessing the impact of the global product approvals and market access based on CE certifications.

Non-compliance to the new requirements within the stipulated timelines will lead to loss of license to market your products in Europe.




**2. Identification of the major compliance requirements**



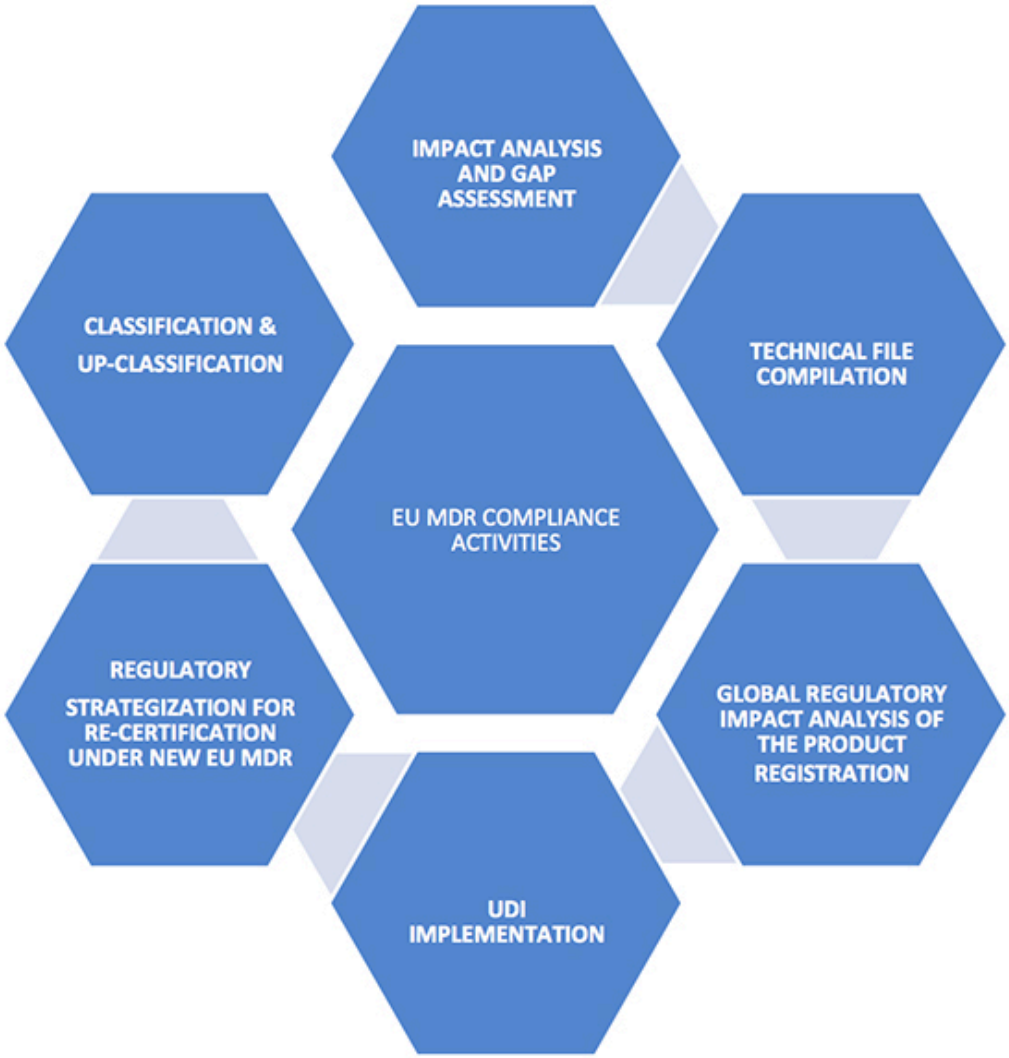

Familiarization of New MDR Terminology: Medical device co-ordination group (MDCG), General Safety and Performance Requirements, Common Specifications, Unique Device Identification, Virtual Manufacturer.

For the products that are newly classified as medical devices as per the new rules, review of the notified bodies will be heightened. New documentation should be made ready for CE

certification as per the new regulations for both reclassified and existing products. Some of the key technical documents that should be in place include:

- Risk analysis documents
- Clinical data availability analysis and plan
- General safety and performance requirements
- Common specifications derivation
- All relevant QA SOPs
- Performance evaluation tests of the device as per the claims
- Labelling updates
- Alignment to the ISO 13485 requirements for manufacturing of the product and certification
- PMCF plans

**3. Gap analysis and strategy finalization for compliance**




**Classification and Up-Classification**

- Classification and up-Classification of the devices as per new EU MDR classification rules
- Classification of non-medical devices/accessories as per new EU MDR classification rules

**Impact Analysis and Gap Assessment**

- Overall impact assessment of the new regulations on the product (Quality/Clinical/QMS)
- Transition plan for recertification of devices as per the new EU MDR (Including re-classified devices)
- Identification of additional requirements for re-certification as per the new EU MDR Assessment of OEM/OBL requirements of technical file (OEM: original equipment manufacturer; OBL: Own Brand Labeler)

**Technical File Compilation**

- Compilation of technical file as per new EU MDR regulations (Including for the accessories/non-medical/software devices/high risk)
- Amendment of technical files for software in accordance with requirements for higher risk class
- Gap analysis of consequences of changed essential requirements and compilation of safety and efficacy summary

**Regulatory Support for Recertification Under New MDR**

- Identification of Notified Body for certification under New EU MDR
- Certification of new devices under New EU MDR
- Re-certification of existing devices and re-classified devices under New EU MDR
- Regulatory strategy for handling of queries from Notified bodies

**UDI Implementation**

- Required for the product right from the submission of application for CE certificate
- Identify the UDI agency for the manufacturer
- Compilation of the UDI requirements for application
- Regulatory strategy on the change of UDI for modifications of the product to manufacturer

**Global Regulatory Impact Analysis of the Product Registration**

- Regulatory intelligence on the impact of the re-certification on global markets where the product is registered based on European certification
- Regulatory strategy and approach to continue the registration status of the product active global markets

## Conclusion

Despite evolving guidelines and interpretations of the new medical device regulations in UDI, EUDAMED, Medical device co-ordination group (MDCG), General Safety and Performance Requirements, Common Specifications, the new EU MDR imposes adherence to tighter safety and efficacy requirements. This raises the bar for regulatory evaluation and certification on par with the unimaginable progression of the medical science innovation. Manufacturers should assess the impact of these changes early during R&D, design development and design scale up, to ensure that the manufacturing and commercialization of the products comply with EU regulations.

## About The Author

**Medical Devices Strategy Expert**
**Freyr**

Shilpa Gampa is a medical devices strategy expert at Freyr with experience in handling borderline products and strategy design for approval, orthopedic devices, ophthalmic devices, contraceptives, wound care products and devices as software including artificial intelligence algorithms. With a comprehensive work experience in medical devices domain, Gampa has a keen interest in tracking new regulations and their implementation to analyze how they impact business factors in the current scenarios, so as to suggest operational pathways for the manufacturers.