WHITE PAPER

IS YOUR PRODUCT PORTFOLIO READY TO TACKLE THE NEW EU MDR REQUIREMENTS? (PART 1)

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Executive Summary

Safety issues with already approved devices such as the hip implant recalls in 2010, breast implant crisis in 2012, necessitated the Council of the European Union (EU) to propose changes to the existing medical devices directives which is being replaced by the Medical Device Regulations (MDR). Current changes comprise of enhanced scope for regulated devices, better supervision and control of notified bodies (NBs), unplanned audits of suppliers and more. For most medical device companies, these changes will have a direct impact on the product review and certification procedures and are likely to increase time investment and resource requirement for product approval. These new regulations directly impact the manufacturers of in-vitro diagnostic medical devices and various other types of medical devices.

The global medical devices market size was USD 432.23 billion in 2020. It was projected to grow from USD 455.34 billion in 2021 to USD 657.98 billion in 2028 at a compound annual growth rate (CAGR) of 5.4%. The European medical device market represents about 30% of the global market and all medical devices sold in Europe could be subject to NBs approval under new regulations.

How does it impact…How to get ready?

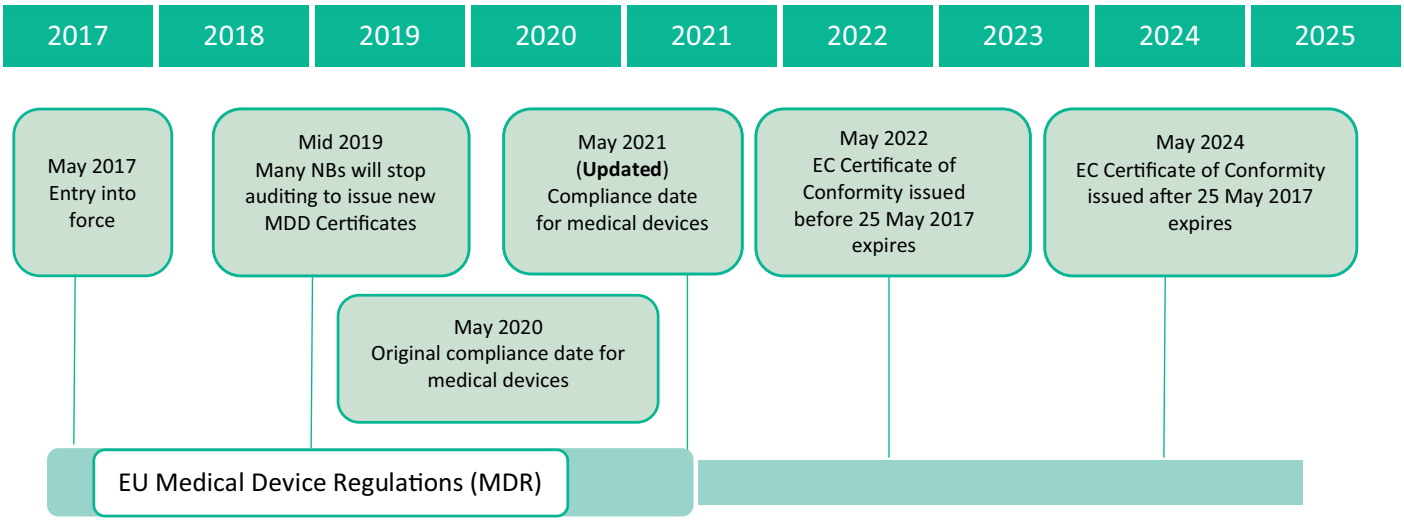
This is the time for companies to take charge of new medical devices regulatory environment, from complex regulations to impactful regulations, by gradually adopting and complying their existing and future product portfolio within the given time span. The impact of MDR can affect the medical device manufacturer operations in the EU and their product portfolio. It is imperative now for businesses to act, prepare, and implement changes in their organization. If companies are non-compliant to these regulations, then they are likely to lose license to operate.

In April 2017, the EU adopted the new MDR 2017/745 and In-Vitro Diagnostic Regulations (IVDR 2017/746). This new regulation MDR 2017/745 has replaced the two existing directives – the Medical Device Directive (MDD) 93/42/ European Economic Community (EEC) and the Active Implantable Medical Device Directive (AIMDD) 90/385/ EEC. After four years of transition period, the new MDR has come into effect from **26 May 2021.**

Similarly, the IVDR will fully replace the existing In-Vitro Diagnostic Directive (IVDD) 98/78/ European Commission (EC) upon its implementation. It has five years of transition period. IVDR 2017/746 was published on 05 May 2017, in the Official Journal of the EU, and had officially gone into effect on 25 May 2017; that means we are almost towards the end of the transition period. During the transitional period, manufacturers can fulfill either IVDD or IVDR requirements. However, **starting 26 May 2022, all new IVDs devices should comply with IVDR.** Some of the devices which received IVDD certificates lawfully have another two years of grace period and may continue to sell until 27 May 2025 (depending on multiple factors).

Timeframe offered to frame your compliance strategy (MDR 2017/745)

On 24 April 2020, the European Commission extended the date of application for EU MDR by 12 months considering COVID-19, which means medical device companies had until 26 May 2021, to comply with the MDR.



EU MDR Transition Timeline

Certificates issued by NBs in accordance with Directives 90/385/EEC and 93/42/EEC from 25 May 2017 shall remain valid until the end of the period indicated on the certificate, which shall not exceed five years from its date of issuance. They shall however become void on 27 May 2024 at the latest.

As a result of Brexit, the UK Conformity Assessed (UKCA) mark is introduced. On 30 Jun 2023, Conformité Européenne (CE)-marked devices must be compliant to the new legislation, and must possess the UKCA, and this is the big relaxation to companies who wish to operate in the UK.

Conclusion

Medical device manufacturers are in various stages of adopting EU MDR and it is very important to focus on product portfolio readiness and conformity ensuring compliance with changes in regulations. This will help to avoid disruption of product pipeline in the global market. Infosys expertise will extend beyond defining & implementing the product portfolio strategy and roadmap.

About the Authors

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Rahul has 10+ years of extensive Regulatory Affairs experience in the Life science domain (Pharmaceutical I Medical Devices I Biologicals). His expertise lies in Regulatory Operations (Submissions and Lifecycle Management, RIMS, Publishing and Medical Devices – Technical File preparation and remediation, Gap Analysis), change management, project management and QMS. He has also worked in the Computer System Validation (CSV) space. He is certified with Veeva Platform Associate white belt and EU MDR 2017/745 from BSI.

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References

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance)

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