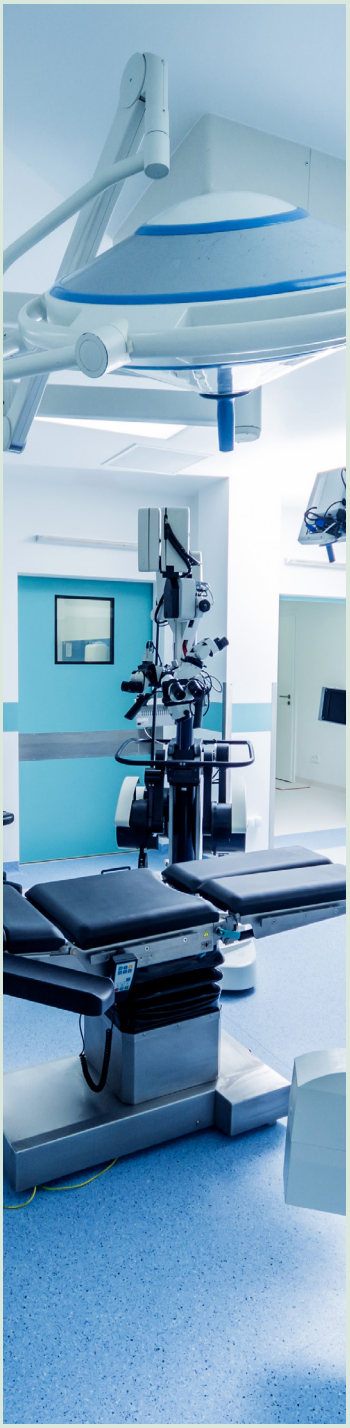
WHITE PAPER



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

New Regulatory Environment of Medical Devices

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Introduction

In Is Your Product Portfolio Ready to Tackle the New European Medical Device Regulations (EU MDR) Requirements (Part 1), we had discussed the necessity, adaptation, and timeline of the new EU MDR changes proposed by the European Parliament and the Council of European Union (EU) to focus on product portfolio readiness and conformity ensuring compliance with changes in regulations. In Part 2, you'll be familiarized with all the new changes and our offerings.

Get Familiar with the New Changes (Medical Device Regulation [MDR] 2017/745)

a. Regulatory scope extension

i. Both 2017/745 (medical devices and active implantable medical devices) and 2017/746 (In-vitro diagnostic medical devices) **have extended the scope of medical and In-Vitro diagnostic devices** being regulated by the EU

ii. Recent regulated medical devices are expected to comprise implants for aesthetic uses, products for genetic testing, specific medical software, and a few high-risk devices manufactured to be used within a single health organization

b. Reinforced regulations covering clinical investigations

i. MDR 2017/745 will require **manufacturers to provide a summary of safety and clinical performance** to support pre-market applications for medical devices **having medium to high risk or high risk to patients,** and **to maintain post-market data for ongoing assessment of potential safety risks**

ii. **Clinical evidence is required to be updated for existing current medical devices,** and a clinical evaluation summary with clear evidence should be made publicly available

iii. The clinical evaluation and its documentation shall be **updated throughout the life cycle** of the device concerned with clinical data obtained from the implementation of the manufacturer's Post-Market Clinical Follow-up (PMCF) plan. For class III devices and implantable devices, the PMCF evaluation report and, if indicated, **the summary of safety and clinical performance** shall be updated at least annually with such data

iv. **Clinical evaluation report (CER)** should document a clinical evaluation, its results, and the clinical evidence derived from it which excludes custom-made devices. This shall be part of the technical documentation relating to the device concerned

v. For implantable devices and for Class III devices, manufacturers must create a summary of safety and clinical performance. The summary must be written clearly to the intended user - and, if relevant, to the patient - and shall be made available via European database on medical devices **(EUDAMED)**

vi. The sponsor or investigator should store all recorded, processed, and handled clinical investigation information so that it can be accurately reported, interpreted, and verified while the confidential records and the personal data of the individuals remain protected as per the law of personal data protection

vii. All clinical investigation information shall be recorded, processed, handled, and stored by the sponsor or investigator, as applicable, in such a way that it can be accurately reported, interpreted, and verified while the confidentiality of records and the personal data of the subjects remain protected **in accordance with the applicable law on personal data protection**

c. Additionally, the **EU General Data Protection Regulation (GDPR)** is a stringent regulation related to data protection and privacy specifically for EU residents. One significant change introduced by the GDPR is a broader definition of personal data, which now includes information about factors specific to an individual's physical, physiological, genetic, mental, economic, cultural, or social identity.

Classification & Implementation

a. Updated classification structure implementation for medical devices

i. Medical Device Directive (MDD) offered the rule-based classification system for medical devices in Europe with 18 rules available in Annex IX. However, the structure of rules is replicated in MDR with the addition of a few more rules. There are now 22 rules in Annex VIII of the MDR

ii. Medical devices will now be **subject to classification rules** that divide products into four major categories as Invasive Devices, Non-Invasive Devices, Active Medical Devices, and special rules. These devices will be classified into classes I, IIa, IIb, and III, considering the intended purpose of the devices and their inherent risks

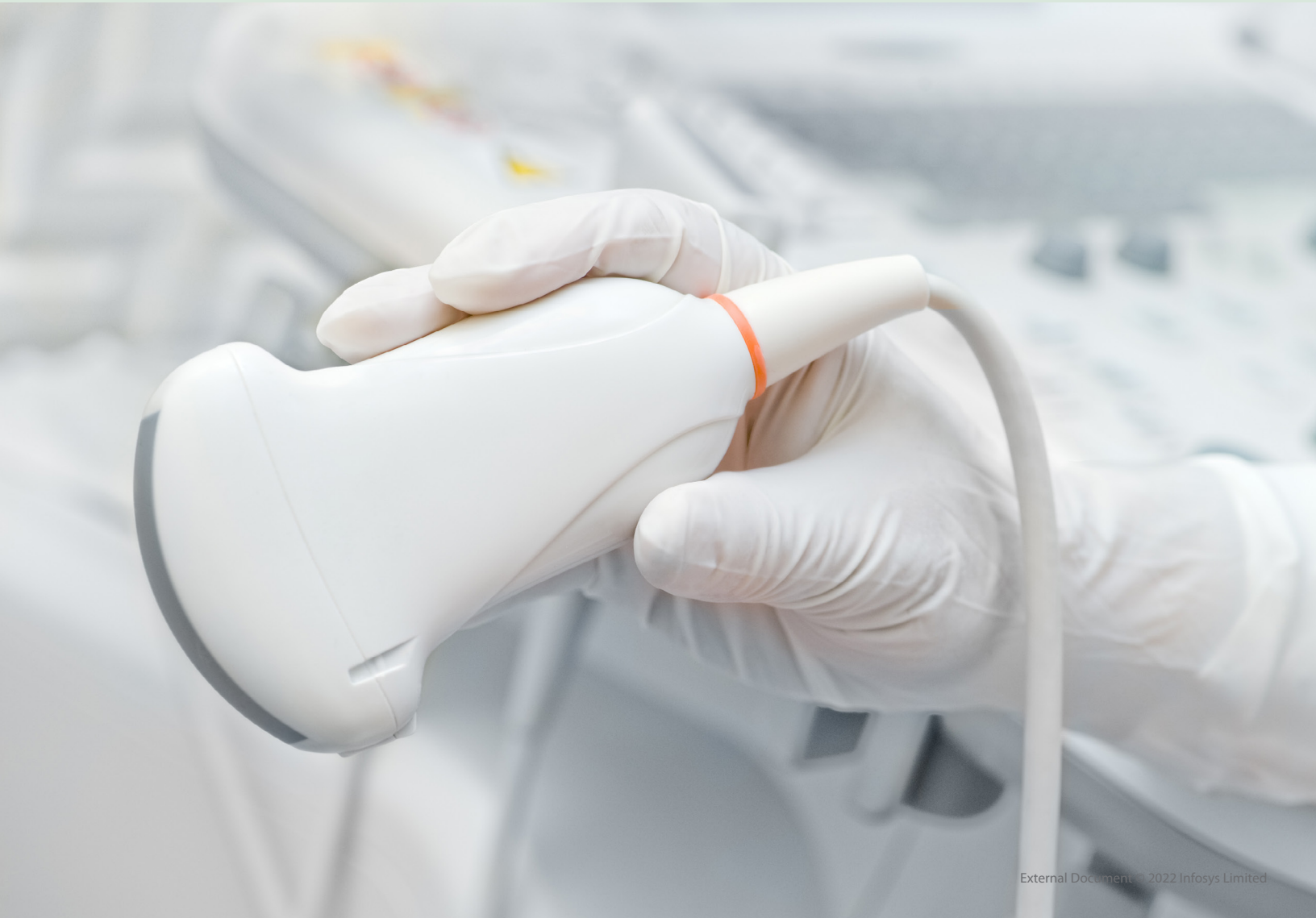
iii. Manufacturers should preserve the **technical documentation,** the EU Declaration of Conformity (DOC), and any relevant certificate copy, any amendments, and supplements, issued as per Article 56, available for the notified bodies (NBs) or competent authorities for at least 10 years after the last device covered by the EU DOC has been placed on the market. The period would be at least 15 years for implantable devices

b. Implementation of Unique Device Identification (UDI)

i. MDR introduced the use of the UDI system to enhance **device traceability through the supply chain,** and to **make product recalls** easier in the event of a safety issue

ii. The UDI system shall be referenced in pharmacovigilance (PV) reports and will be used for documenting or reporting serious health incidents and field safety corrective actions. Additionally, implant cards with warnings and information regards to expected device shelf life and important follow-ups will be required for implantable medical devices

iii. Custom-made devices should be identified by names, an acronym, or a numerical code while making them available to specific patients



People

a. Role of "qualified persons"

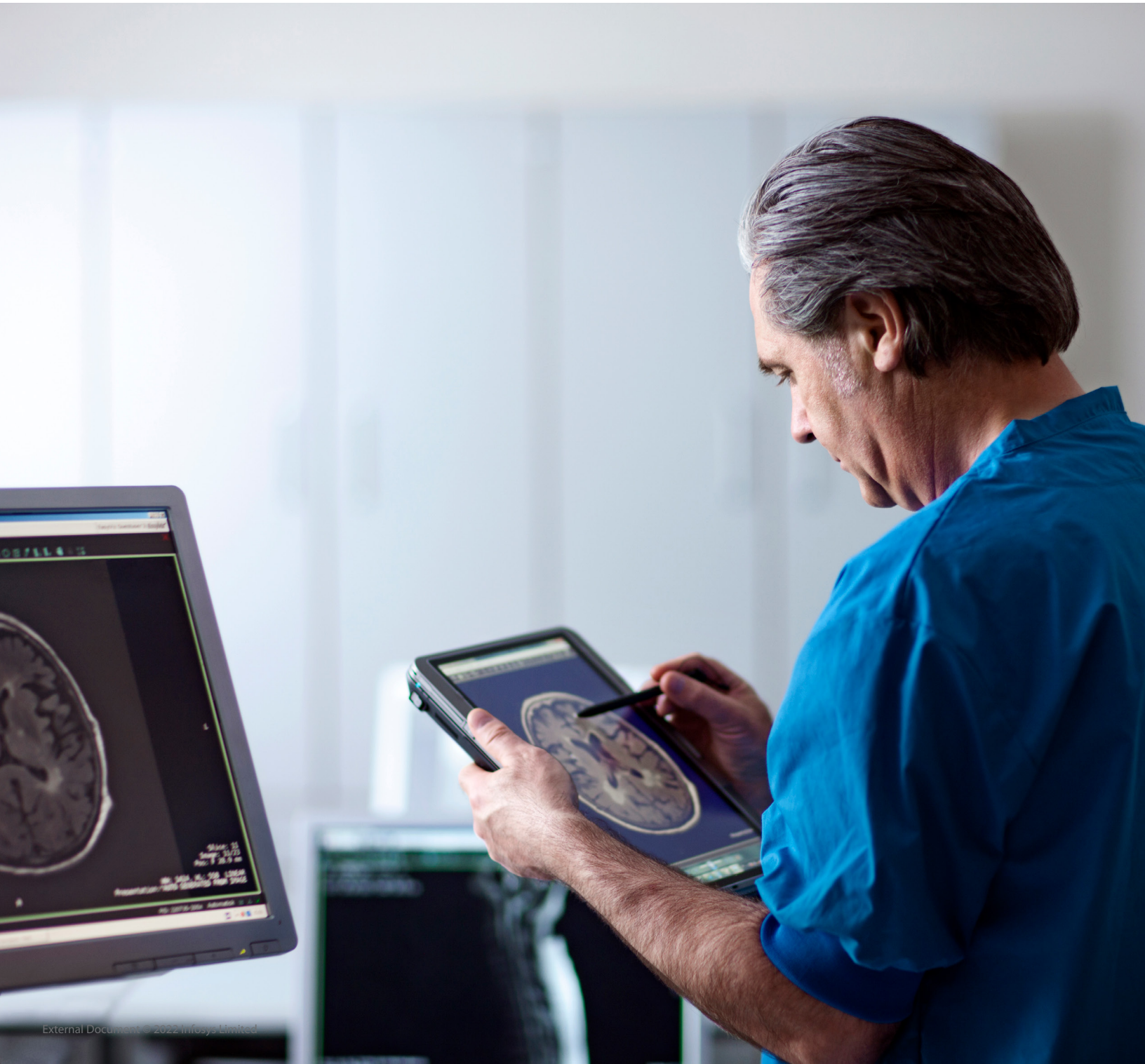
i. Manufacturers should have **at least one individual responsible for all requirements of regulatory compliance** within their organization. This "qualified person" must have the experience and necessary skillset appropriate for this task

ii. **Economic operators** comprise **manufacturers, EU Authorized Representatives, importers, and distributors, and** all these carry responsibilities for compliance with the regulations

iii. Manufacturer should designate an authorized representative if the manufacturer is not established in the European Union member state

b. Greater coordination

i. The goal of the **Medical Device Coordination Group (MDCG)** is to **facilitate coordination between EU member states** regarding medical device regulation and surveillance, with scientific, technical, and logistical support provided by the EU Commission



Process

a. **Expanded registration database of devices**

MDR proposed to expand the **EUDAMED** use to **provide a centralized repository of information** on approved medical devices for regulators and end-users. **EUDAMED** expansion will enable public awareness of the list of authorized devices in the EU market and the corresponding certificates issued by notified bodies to the relevant economic operators

i. The UDI database is designed with multiuser access, having provisions for automatic uploads and downloads of stored information. It also ensures maximum accessibility to the content

b. **Stronger post-market vigilance and surveillances**

i. NBs are granted **increased authority to conduct post-market product testing and sample checks,** including unannounced factory inspections at manufacturing locations

ii. Increased vigilance issues, reported field complaints or other product concerns may result in **additional unannounced audits**

iii. New regulations associated with vigilance and post-market surveillance, affecting national authorities and economic operators, include **the establishment of an EU database on Medical Devices**

iv. The **database captures** registration of devices, accredited NBs, Certificates, Serious Incidents, Safety and Clinical Performance Reports (SSCP), Periodic Safety Update Reports (PSUR), Surveillance Activities, Clinical Investigation Data, UDI, and Single Registration Information to correlate information from the manufacturer, authorized representative, and importer

v. Manufacturers shall **report, by means of the electronic system, any statistically significant increase in the frequency or severity of incidents** that are not serious incidents or that are expected undesirable side-effects that could have a significant impact on the benefit-risk analysis, and which have led or may lead to risks to the health or safety of patients, users or other persons that are unacceptable when weighed against the intended benefits

vi. The manufacturer shall **specify how to manage the incidents** referred to in the first subparagraph and the methodology used for determining any statistically significant increase in the frequency or severity of such incidents, as well as the observation period, in the post-market surveillance plan

c. **Increased regulation and oversight of NBs**

i. NBs are subject to adhere to **new minimum requirements to obtain and maintain the designation.** These NBs are supervised and monitored **more rigorously** by **national authorities** through audits and other mechanisms

ii. MDR enlists the **more demanding requirements** for NBs which include a **stricter accreditation process:** Current NBs must be **re-certified** under the new regulations

Quality, Risk & Compliance

Manufacturers should consider the below requirements to adopt the changes to safety and performance requirements:

a. **Demonstrating compliance** through risk management, testing, and technical studies

b. **Maintaining the system** for recording, reporting incidents, and field safety corrective actions to maintain the conformity of the device

c. The **quality management system** shall cover all parts and elements of a manufacturer's organization dealing with the quality of processes, procedures, and devices. It shall govern the structure, responsibilities, procedures, processes, and management resources required to implement the principles and actions necessary to achieve compliance with the provisions of this Regulation

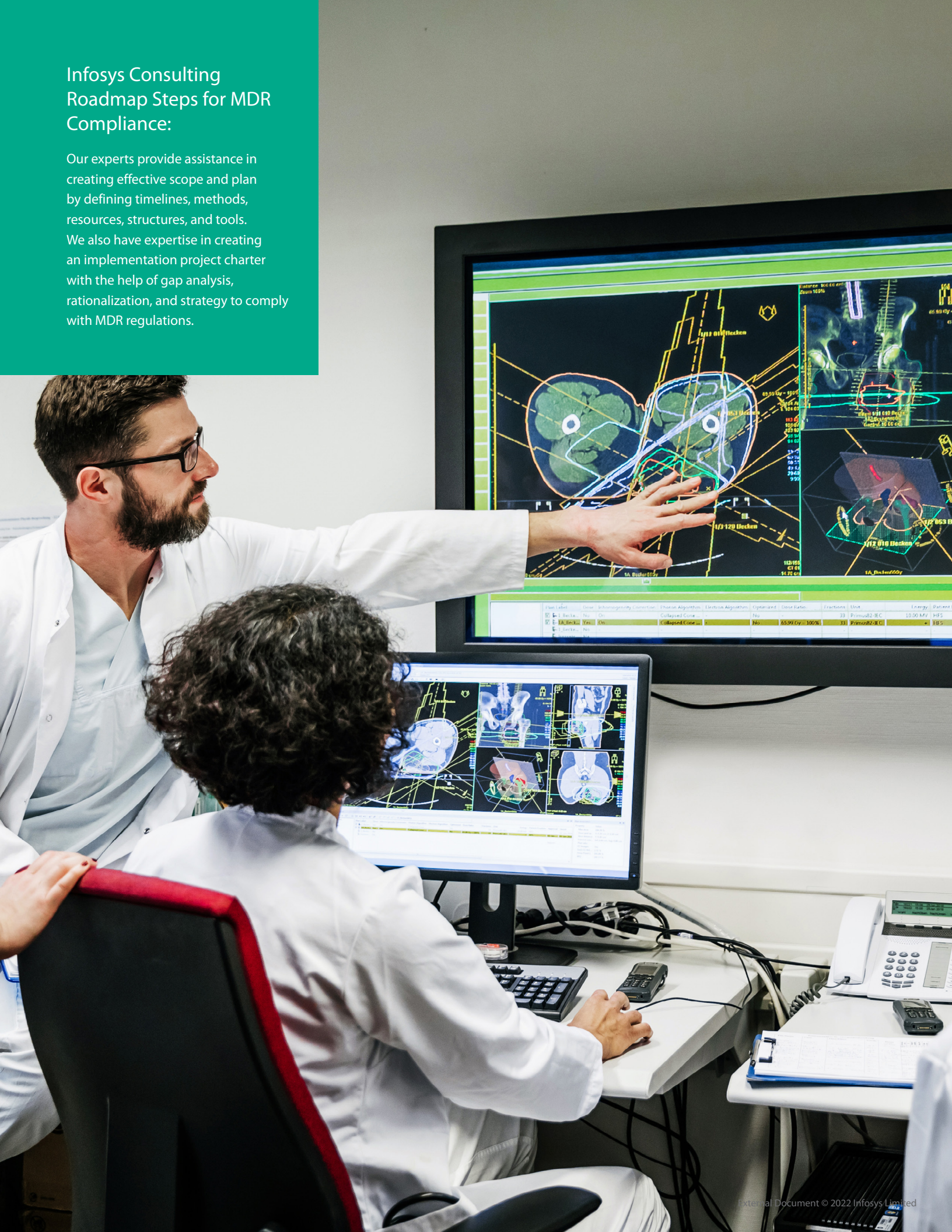
Conclusion

All manufacturers from the medical devices' portfolio should be compliant with the revised EU MDR guidelines.

The Infosys Consulting EU MDR roadmap can be tailored to the specific needs of manufacturers as it is a time-consuming process, starting from the implementation of MDR to getting the new MDR CE certificates.

Infosys Consulting Roadmap Steps for MDR Compliance:

Our experts provide assistance in creating effective scope and plan by defining timelines, methods, resources, structures, and tools. We also have expertise in creating an implementation project charter with the help of gap analysis, rationalization, and strategy to comply with MDR regulations.



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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)
- Is Your Product Portfolio Ready to Tackle the New MDR Requirements? (Part-1)

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