ARE YOU READY FOR EU MDR 2017/745-746 ?

We support your **medical device company** in the transition process

EU MDR GUIDE

by

PQE GROUP

GLOBAL **QUALITY** SOLUTIONS

ARE YOU READY FOR EU MDR 2017/745-746 ?

Medical Devices Today.

Today's European MD market consists in more than 500,000 types of medical devices and in-vitro diagnostic medical devices. The range includes several type of Medical Devices, like machines, single use, implantable devices, sticking plasters, standalone software etc. The MD industry also includes in vitro diagnostic medical devices, such as blood tests, pregnancy tests and monitoring systems.

The former regulatory framework, dated back to the 90s, and consisted of three Directives that encountered interpretation problems leading to weaknesses, thus mining the confidence of patients, consumers and healthcare professionals in the safety of medical devices.

The new regulations were therefore issued to strengthening the safety of all medical devices and to encompass new technologies. The Regulations, with the scope to provide high level of health and safety protection for EU citizens, retain all the requirements of the current Directives, and add some new obligations.

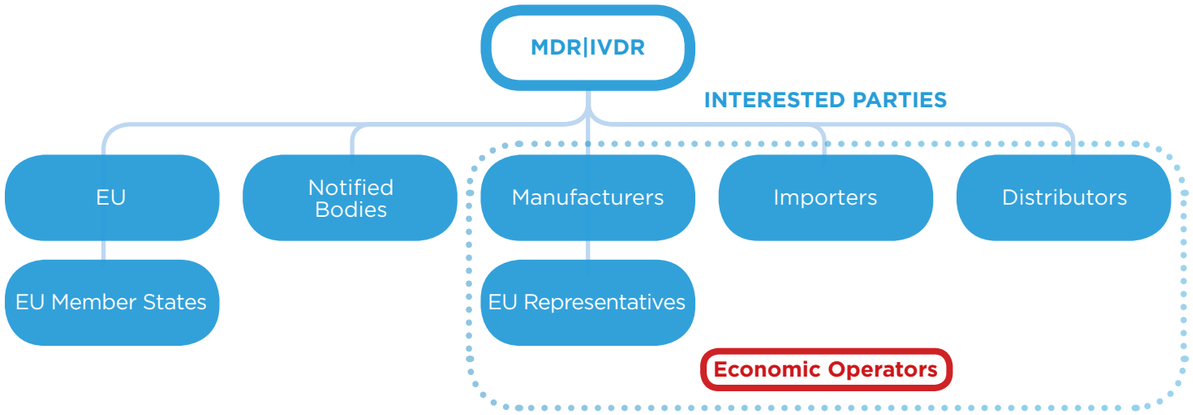
ARE YOU READY FOR **EU MDR 2017/745-746?**

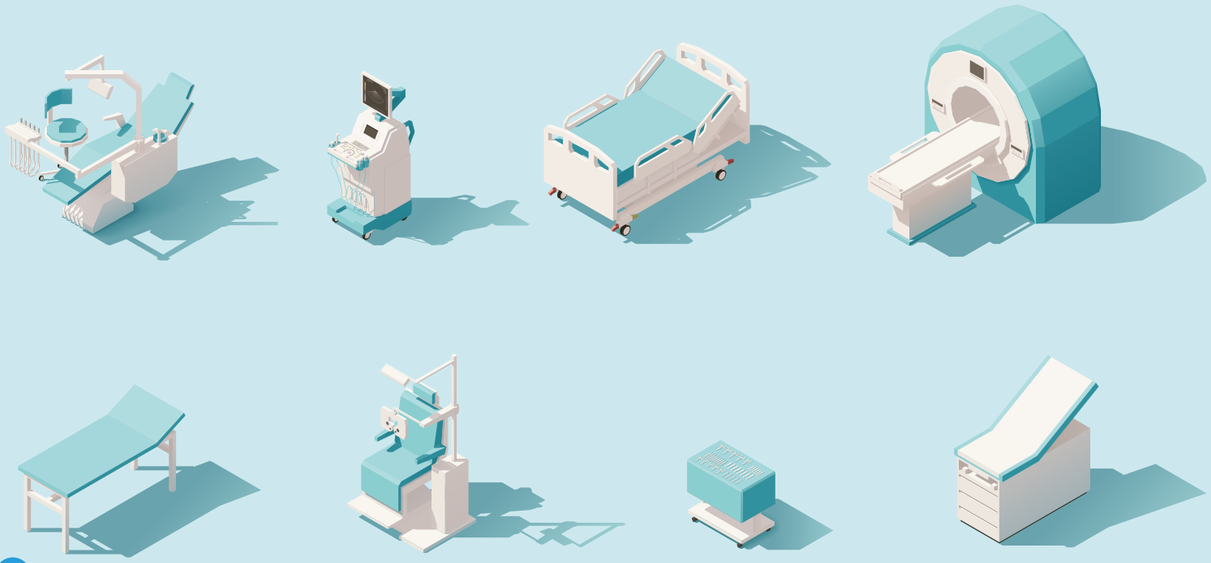
On 26 September 2012 two legislative proposals addressing MD and In-Vitro were proposed at the European Commission, followed by extensive expert consultations resulting in an agreement stipulated on 5 October 2015 among Member States' health ministers on the general approach to the medical devices package, leading to the issuing of the new EU-MDR Regulations in 2017.

Issued officially on May 25, 2017, the EU MDR 2017/745 introduced new regulations for the Medical Devices sector, to establish a modern EU legislative framework and ensure better protection of public health and patient safety: Regulation 745/2017 (MDR) concerning medical devices, repealing Directives 90/385 / EEC and 93/42 / EEC, and Regulation 746/2017 (IVDR) related to in vitro diagnostic devices.
The new regulations will apply after a transitional period: on May 26th 2020 for medical devices, and on May 26th of 2022 for in-vitro diagnostics.

The new regulations will apply after a transitional period: on **May 26th 2020** for medical devices, and on **May 26th of 2022 for in-vitro diagnostics**.

* reference





PQE GROUP

An epochal change **for the MD industry.**

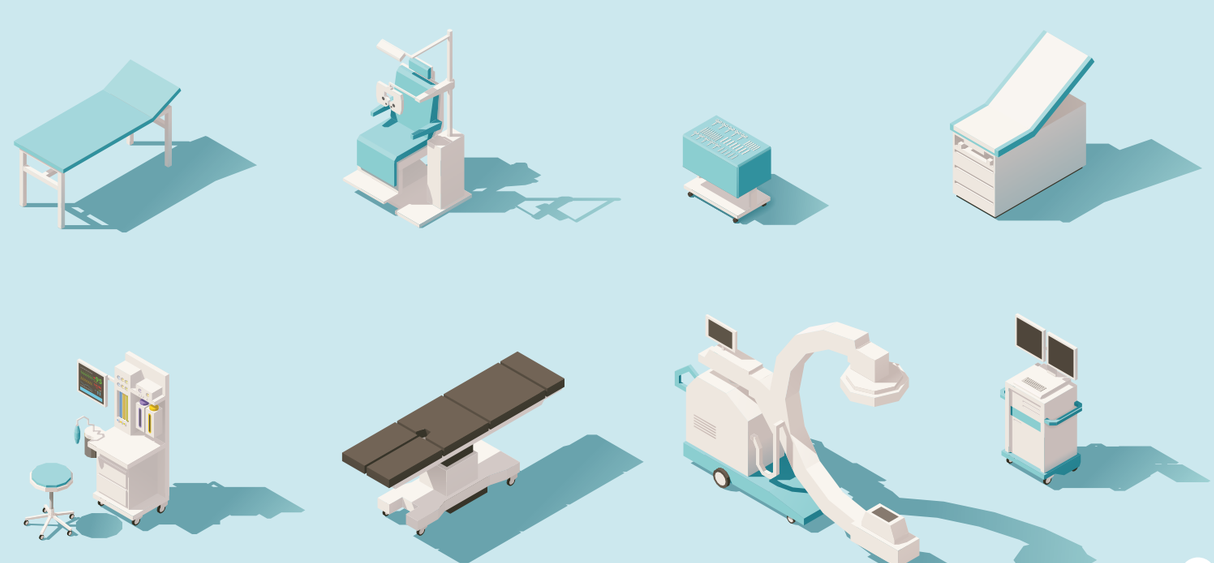
The new Regulations clarify the obligations of the Economic Operators (Manufacturers, Authorized Representatives, Importers, and Distributors) placing their products on the European market.
This revision of the legislation was also a strategic driver to consolidate the role of the EU as a global leader in the MD sector over the long-term, concerning all technological and scientific developments of its competence.

The new regulations were issued to ensure:

- a consistently high level of health and safety protection for EU citizens using these products (*)
- the free and fair trade of the products throughout the EU (*)
- that EU legislation is adapted to the significant technological and scientific progress occurring in this sector over the last 20 years (*)

The Commission is also aiming to develop a wider goods package reform for a better market surveillance, with structural and horizontal reforms. (**)

* source ** source



MAY 26TH **2020** for medical devices, and on **MAY 26**TH of **2022** for in-vitro diagnostics

ARE YOU SUBJECT TO EU MDR 2017/745-746 ?

The MDR includes a set of new stakeholders subject to its rules: **manufacturers**, **authorised representatives**, **importers** and **distributors of medical devices in the EU** must now comply, as well as regulatory affairs or quality management professionals involved with medical devices. If you or your company are part of these subjects, **you must be prepared with the necessary knowledge and support to comply**.

READ THE FULL EU-MDR 2017/745 **TEXT HERE**

Manufacturers

EU Representatives

Importers

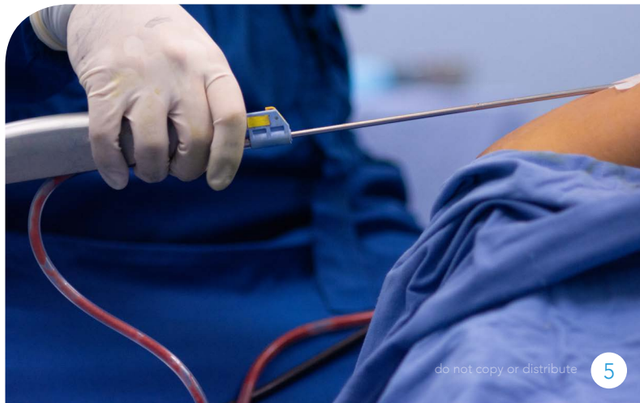
Distributors

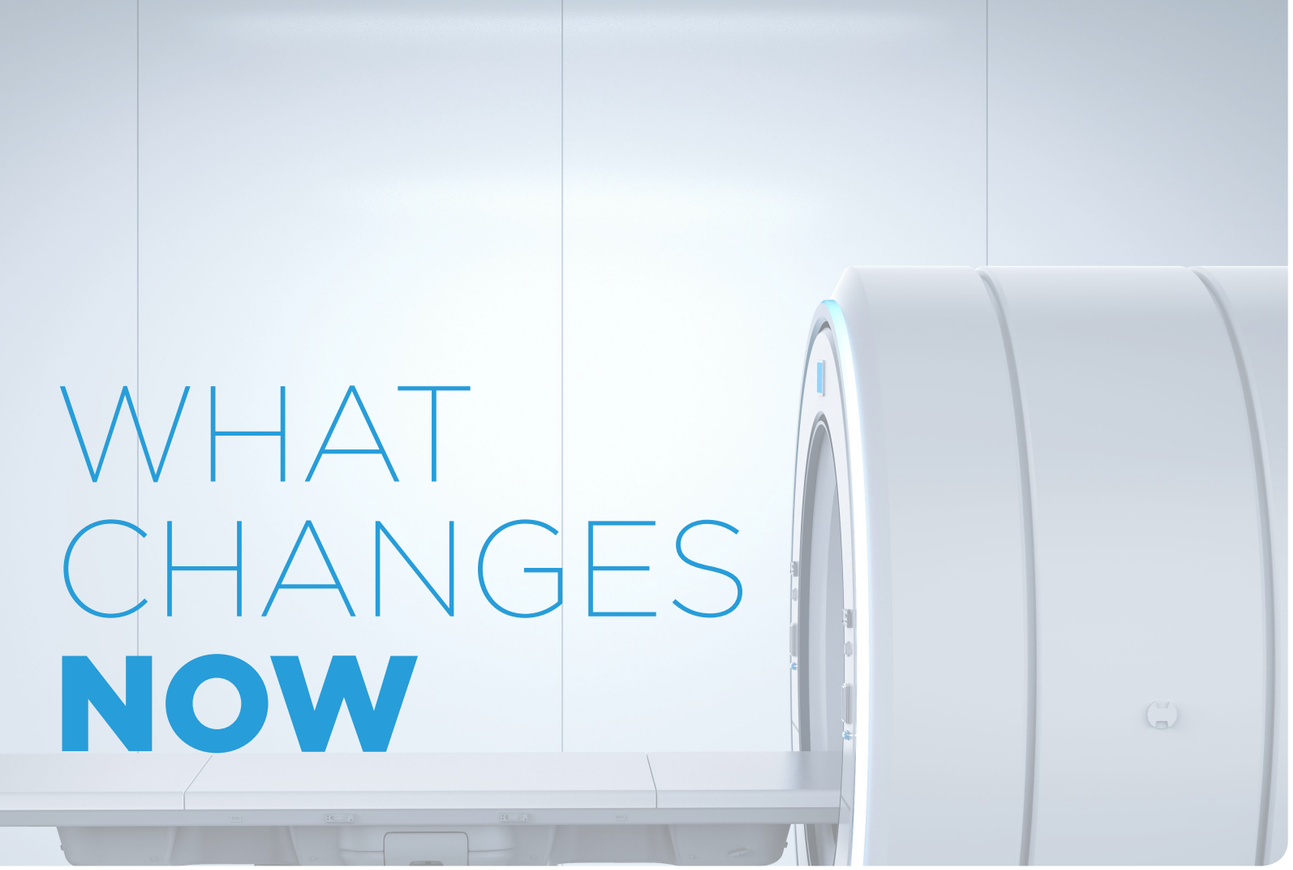
An extended MD products coverage

MDR 2017/745 ANNEX XVI and Art 1(2)

extended the scope also to the GROUPS OF PRODUCTS WITHOUT AN INTENDED MEDICAL PURPOSE.

The inclusion under the scope of the MDR of aesthetic devices, having the same risk profile as medical devices, extends the obligation to many companies, until now not familiar with the medical device Requirements.





WHAT CHANGES **NOW**

A series of game-changing improvements are contained in the new EU-MDR regulations, including:

- pre-market scrutiny mechanism, to grant a strict ex-ante control of high-risk devices, involving of a pool of experts at EU level
- Designation and Processes criteria reinforcement for the Notified Bodies' oversight
- Inclusion of aesthetic devices presenting characteristics and risk profile similar to analogous medical devices undergoing the mentioned Regulations
- Introduction of a new risk classification system for in vitro diagnostic medical devices
- Establishment of a comprehensive EU database on medical devices and device traceability system based on Unique Device Identification, to improve transparency
- "Implant card" containing a patient's implanted medical devices profile
- EU-wide coordinated procedure for multi-centre clinical investigations authorization, plus the reinforcement of the rules on clinical evidence.
- Post-market surveillance requirements for manufacturers are reinforced
- EU countries' coordination in vigilance and market surveillance procedures is improved

Significantly reinforced are the Clinical Evaluation requirements, such as the post-market clinical follow-up, which is intended as a continuous process that updates the clinical evaluation, as well as vigilance and post-market surveillance requirements.

MDR key changes

- Person responsible for Regulatory compliance
- Reclassification of devices according to risk, contact duration and invasiveness
- Rigorous post-market oversight
- Common Specification
- Implementation of unique device identification
- Recording and Reporting Incidents
- New Requirements both for compliance and NB
- Systematic clinical evaluation for all MD more rigorous Clinical Evidence for class III and implantable devices
- Manufacturer and device registration
- Devices without a medical intent

NEW RISK CLASSES:

The MDR sets out new rules for determining risk classes, as a consequence Class I devices may be upper-classified and may require the intervention of a **Notified Body**.

Modifications in classifying rules could lead to some devices reclassification → Manufacturers shall verify if the classification rules are still applicable → MDR Regulates the disputes about classification between Manufacturers and NB

Is your MD to be re-classified?

The new ANNEX I GENERAL SAFETY & PERFORMANCE REQUIREMENTS

Annex I of MDR specifies the General Safety and Performance Requirements, while Annexes II and III specify the requirements of the technical and post market surveillance documentation. As a result, the technical file of legacy devices shall be updated providing evidence of the fulfilment to the new Regulations requirements.

MORE REQUIREMENTS (23 VS 13)

DIFFERENCES IN FORMULATION OF REQUIREMENTS

ALTERED STRUCTURES

GSPR Assessment on your legacy device shall be planned

- TD must be compliant to new essential requirements
- Pay attention to new enhanced requirements
- New evidences must be provided to confirm the compliance to the new essential requirements

WHAT TO DO PREVENT YOUR PRODUCT FROM BEING **BLOCKED**

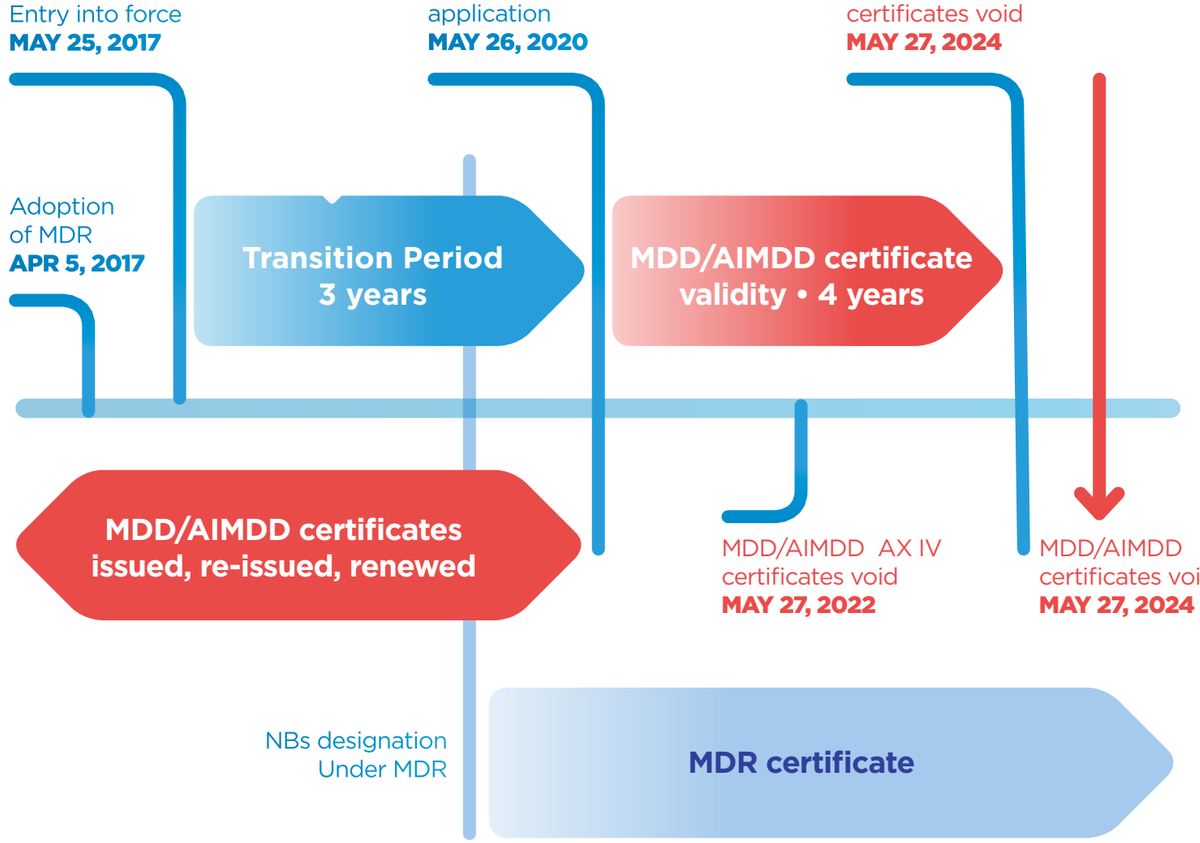
Being ready for the transition becomes crucial. The medical devices companies economic operators in general shall get be prompt by preparing the transition plan, identifying discrepancies, allocating resources to manage the identified gaps.
The gap analysis is already a must to face the NB inspections.

- **Clinical evaluation - PMCF**
- **New essential requirements**
- **PMS e vigilance**
- **Recording and reporting incidents**
- **Technical Documentation Specif.**
- **UDI System Implementation**
- **Registration of devices**
- **Person responsible for compliance**
- **New Conformity Assessment**
- **Notified body Requirements**
- **Devices without a medical intent**
- **New Classification Rules**

PQE GROUP

EU MDR ENFORCEMENT TIMELINE

Early planning of timings and modalities for the release of the new EC Certificate with the designated Notified Body is essential to ensure uninterrupted circulation of the products in the European market.



SOLUTIONS

PQE Group supports all the “Economic Operators” in the transition period, carrying out gap analysis, preparing transition plan and reviewing the Technical File, for new and existent medical devices and in vitro diagnostic of all classes, focusing on the high-risk devices, building compliance since the beginning of the design and development phase.

- **Technical File assessment and gap analysis**
- **Transition plan**
- **Training on new requirements**
- **Support to new requirements implementation**
- **Clinical Evaluation**
- **PMS – PMCF**
- **UDI**

... AND MUCH MORE

CONTACT US TO KNOW MORE ABOUT **EU-MDR** 2017/745-746

CLICK HERE

DON’T WAIT!
A team will be available to evaluate the best tailored solutions for your business by PQE Group.

PQE GROUP
GLOBAL **QUALITY** SOLUTIONS

Choose **PQE Group,**
we support you
globally, thinking locally.

HEADQUARTERS
Località Prulli, 103/C • 50066
Reggello (Florence) ITALY
T +39.055.5275100 • F +39 055.5275142

pqegroup.com
info@pqegroup.com

FOLLOW US ON: