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
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.

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.

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.

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

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 (*)

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**note**
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

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 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

MORE REQUIREMENTS (23 vs 13)

DIFFERENCES IN FORMULATION OF REQUIREMENTS

ALTERED STRUCTURES

Is your MD to be re-classified?

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.

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
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.

**WHAT TO DO**

**PREVENT YOUR PRODUCT FROM BEING BLOCKED**

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

**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.

- **Entry into force** MAY 25, 2017
- **Adoption of MDR** APR 5, 2017
- **Transition Period** 3 years
- **Date of application** MAY 26, 2020
- **MDD/AIMDD certificate validity** • 4 years
- **MDD/AIMDD certificates issued, re-issued, renewed**
- **MDD/AIMDD AX IV certificates void** MAY 27, 2022
- **MDD/AIMDD certificates void** MAY 27, 2024
- **NBs designation Under MDR**
- **MDR certificate**
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

DON’T WAIT!
A team will be available to evaluate the best tailored solutions for your business by PQE Group.
Choose PQE Group, we support you globally, thinking locally.