Medical Device Regulation Compliance

Quick Check

Big changes lie ahead: On 5 May 2017, a new European regulation [(EU) 2017/745] was published imposing significantly stricter and more comprehensive compliance requirements on companies in the medical device sector. The spreading of COVID-19 forced the lawmakers to postpone the date of application to May 2021.

In fact, major changes include an update of classification rules (e.g. software may also count as a medical device) and technical changes, such as registering the device in a centralized European devices database (EUDAMED) to improve traceability (with the help of a Unique Device Identifier) thus improving post-market surveillance.

As a consequence, from May 2021 onwards, devices certified only according to the previously valid EU directives on medical devices (93/42/EEC) and/or the current implantable medical devices (90/385/EEC) can no longer be sold or distributed in the European Union.

This gives companies a bit more time to prepare and tidy up loose ends. Nevertheless, this means a lot of additional work for companies which cannot be covered in parallel to the daily business operations.

KPMG can support your process to become MDR-compliant by challenging you on the regulation´s core requirements by evaluating your company's level of maturity including the technical implementation:

- From a regulatory perspective, this includes aspects regarding classification, conformity assessment, unique device identifier, process validation, supply chain analysis, and post-market surveillance/safety.
- From a technical perspective, this addresses aspects such as EUDAMED/FDA, quality management systems, surveillance assessment, additional IT components (DMS), data integrity as well as access management.

Your Benefits

Profit from an early identification of investment gaps, potential for process optimization and related next steps.

Build on KPMG's international network of experts from various relevant fields, such as the medical industry, technology, processes, risk, and more.

Rely on KPMG's significant expertise in working with European regulatory bodies and the implementation of complex requirements.

KPMG helps lift the fog

KPMG provides invaluable insights on market access, compliance and regulatory affairs that helps to identify potential gaps, thus allowing you to invest in high-risk areas previously undetected:

– Our comprehensive survey is discussed in a workshop used to clarify issues and document results. Alternatively, it could also be done digitally. The questionnaire itself consists of approx. 90 detailed topics divided into the four primary dimensions (as shown in the figure below) as well as twelve sub-dimensions. This enables a targeted evaluation of your company's level of maturity and allows to-the-point recommendations for an action plan.

This is how it works during COVID-19

– KPMG is fully aware that it is currently not easy or advisable to hold a workshop in person.
– This is why the MDR Compliance Quick Check was developed on our KPMG survey platform, which adheres to the highest IT security and data protection standards.
– KPMG communicates using Skype for Business and Microsoft Teams, so the assessment, the analysis of results and the definition of next steps are completely digital and no personal contact is required.

Dimensions to consider

Applicability

Depending on the type of product, we will analyze the applicability of relevant classification for medical technology products as defined in the new MDR. Products are classified to reflect, among other things, the risk of a product defect occurring. One of the dimensions also reviews which requirements are particularly relevant for your portfolio to operate in the European market.

Organization

– Implementing the MDR regulations is complex and requires large internal structures and resources that can carry out the project in accordance with the guidelines. Our questionnaire helps you get an overview of what you have already done and how much more needs to be done to be fully MDR-compliant.
– We focus on organizational measures that are essential to fulfill related requirements and how you can include them in your internal control system.

Documentation

– Technical documentation that is MDR-compliant is a basic prerequisite for a successful approval of medical technology products. This dimension reviews aspects, such as the required technical documentation, which focuses on all documents that manufacturers of medical devices have to provide.
– The MDR obliges manufacturers of medical devices to enter specific data about themselves and their products in the European database for medical devices (EUDAMED).
– According to the MDR, each medical device should have its own "fingerprint". In the future, every medical device must therefore be clearly identified with a UDI that makes it easy to identify and track.

Process design

– Medical products that were already certified on the basis of the prior rules still have to be re-certified. The reason for this is that the MDR treats all products as new.
– Companies that sell medical devices must continuously and systematically collect data in order to remain compliant with the MDR even once medical devices are on the market. A mature concept for the so-called "post-market surveillance" is therefore indispensable.
– According to the new directive, manufacturers of medical devices are required to collect clinical data both before and after placing their products on the market.

Contacts

KPMG AG
Räffelstrasse 28
PO Box
CH-8036 Zurich

kpmg.ch

Christian Walch
Director
Consulting

+41 58 249-3131
cwalch@kpmg.com

KPMG AG
Wirtschaftsprüfungs-
gesellschaft
Barbarossapl. 1a
D-50674 Cologne
kpmg.de

Dirk Distelrath
Director
Consulting

+49 221 2073-1313
ddistelrath@kpmg.com

The information contained herein is of a general nature and is not intended to address the circumstances of any particular individual or entity. Although we endeavor to provide accurate and timely information, there can be no guarantee that such information is accurate as of the date it is received, or that it will continue to be accurate in the future. No one should act on such information without appropriate professional advice after a thorough examination of the particular situation. The scope of any potential collaboration with audit clients is defined by regulatory requirements governing auditor independence. If you would like to know more about how KPMG AG processes personal data, please read our Privacy Policy, which you can find on our homepage at www.kpmg.ch.

© 2020 KPMG AG is a subsidiary of KPMG Holding AG, which is a member of the KPMG network of independent firms affiliated with KPMG International Cooperative ("KPMG International"), a Swiss legal entity. All rights reserved.