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Índice

Index

1-Editorial

A Cinterqual tem acompanhado de perto a evolução das várias áreas e sectores mais relevantes relacionados com as actividades dos seus clientes, e nesta edição abordamos como tema a Nova da Legislação da União Europeia no sector dos Dispositivos Médicos.

Estivemos mais uma vez presentes na feira MEDICA de 2019 em Dusseldorf, e na Hospitalar 2019 em São Paulo, estabelecemos muitos contactos com os nossos clientes bem como com grande número de novas empresas de várias regiões e países .

A Cinterqual tem alargado a representação na EU de empresas em vários sectores e países, apoiando deste modo a sua internacionalização e a sua entrada nesses mercados, nomeadamente no sector dos Dispositivos Médicos.

O futuro está a ser construído com a participação de todos nós.

Carlos Ganopa

1-Editorial

Cinterqual has closely monitored developments in the various areas and sectors most relevant to its customers' activities, and this issue is addressed as the subject of the Review of European Union Legislation in the Medical Devices sector.We were once again present at the 2019 MEDICA fair in Dusseldorf, and at Hospitalar 2019 in São Paulo, we established many contacts with our clients as well as with a large number of new companies from various regions and countries.

Cinterqual has expanded the representation in the EU of companies in various sectors and countries, supporting their internationalization and their entry into these markets, particularly in the Medical Devices sector. The future is being built with the participation of all of us.

Carlos Ganopa

2-Tema Principal

Revisão da Legislação da União Europeia no Sector dos Dispositivos Médicos

Em 26 de Setembro de 2012 a Comissão Europeia iniciou um processo de revisão das Directivas relativas aos MD e IVD, com o objectivo de substituir as Directivas actualmente em vigor, após o que culminou com a publicação em 2017 da nova Legislação
Reproduzimos em seguida em inglês a informação disponível, com os respectivos links , tendo como base a informação da Comissão Europeia:
https://ec.europa.eu/growth/sectors/medical-devices_en

2-Main Theme

Review of European Union Legislation in the Medical Devices Sector

On 26 September 2012 the European Commission started a process of revision of the Directives on MD and IVD, with the aim of replacing the existing Directives.
We then reproduce in English the available information with the respective links, based on information from the European Commission:
https://ec.europa.eu/growth/sectors/medical-devices_en

"REVISION OF THE REGULATORY FRAMEWORK"

On 26 September 2012, the European Commission adopted a Proposal for a Regulation of the European Parliament and of the Council on i) medical devices and ii) in vitro diagnostic (IVD) medical devices. These regulations, once adopted, will replace the existing three medical devices directives.
The texts of the proposals and other related documents are available on the Revision page
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Background

In 2012, the Commission adopted a package of measures on innovation in health. The package consisted of a Communication and two regulation proposals to revise existing legislation on general medical devices and *in vitro* diagnostic medical devices. In particular, the Directives on active implantable medical devices (90/385/EEC) and on medical devices (93/42/EEC) are intended to be replaced by a Regulation on medical devices, while the Directive on in-vitro diagnostic medical devices (98/79/EC) is intended to be replaced by a Regulation on the same subject.
The revisions therefore affected all kinds of medical devices including in vitro diagnostic medical devices, from home-use items like sticking plasters, pregnancy tests and contact lenses, to X-ray machines, pacemakers, breast implants, hip replacements and HIV blood tests.

New regulations

From contact lenses and sticking plasters to pacemakers and X-ray scanners, medical devices and in vitro diagnostic medical devices are essential to our health and quality of life as well as to the European economy.
We all expect medical devices to be safe and to incorporate the latest progress in science and manufacturing technology. Since the EU's rules on the safety and performance of medical devices were laid down in the late 1990s, however, there have been discrepancies in their interpretation across Europe. Issues have also arisen in some categories of medical devices, for instance breast implants and metal-on-metal hip implants.
To reflect progress over the last 20 years, the EU has therefore revised the legal framework. 2 new regulations – one on medical devices and the other on in vitro diagnostic medical devices – were adopted by the Council and the Parliament, and entered into force in May 2017.
The new rules will only fully apply after a transitional period. That period lasts for 3 years after the entry into force of the regulation on medical devices (i.e. until May 2020), and 5 years after the entry into force of the regulation on in vitro diagnostic medical devices (i.e. until May 2022).
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
Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU
Read the press release from the European Commission

The new regulations in a nutshell

The new regulations contain a series of extremely important improvements to modernise the current system. Among them are

- **stricter ex-ante control for high-risk devices** via a new pre-market scrutiny mechanism with the involvement of a pool of experts at EU level
- **reinforcement of the criteria for designation and processes for oversight of notified bodies**
- **inclusion of certain aesthetic devices** that present the same characteristics and risk profile as analogous medical devices under the scope of the regulations
- **a new risk classification system for** in vitro **diagnostic medical devices** in line with international guidance
- **improved transparency** through a comprehensive EU database on medical devices and device traceability system based on unique devic identification
- **introduction of an 'implant card'** for patient containing information about implanted medical devices
- **reinforcement of the rules on clinica evidence**, including an EU-wide coordinated procedur for authorising multi-centre clinical investigations
- **strengthening of post-market surveillance** requirements for manufacturers
- **improved coordination mechanisms** between EU countries in the fields of vigilance and market surveillance

More information is available in this presentation tha contains general information on key changes containe in the regulations and transitional periods.
See the new rules to ensure safety of medical devices.
All actors involved with medical devices, from thei manufacture to their use, will have to comply with th new regulations by May 2020 (May 2022 for in vitr diagnostic medical devices). **It is important that all actors are fully aware of the changes and start preparing for the implementation of the new regulations as soon as possible.**
On these web pages you will find information targeted at the various actors in the section getting ready for the new regulations and on several horizontal topics in the section topics of interest.
Be aware that the European Commission is not responsible for content provided by non-Commission websites.

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Problems with diverging interpretation of the current Directives as well as the incident concerning fraudulent production of the PIP silicone breast implants highlighted weaknesses in the legal system in place at the time and damaged the confidence of patients, consumers and healthcare professionals in the safety of medical devices. Such problems should not occur again and the safety of all medical devices available in the EU has to be strengthened. Moreover, revision of the legislation was necessary to consolidate the role of the EU as a global leader in the sector over the long-term and to take into account all technological and scientific developments in the sector.
The new regulations will 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

Corrigenda to the medical devices regulations

- Corrigendum to Regulation (EU) 2017/745 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Directives 90/385/EEC and 93/42/EEC
- Corrigendum to Regulation (EU) 2017/746 on in vitro diagnostic medical devices, repealing Directive 98/79/EC and Commission decision 2010/227/EU

ROADMAP


2017 2018 2019 2020 2021 2022 2023 2024 2025
Transition period
Sunset period
Year 0 Year 1 Year 2 Year 3 Year 4 Year 5 Year 6 Year 7 Year 8
Entry into Force:
2017-05-25
Date of Application:
2020-05-26
MDD/AIMDD to MDR transitionperiod
MDD Certificates issued during transition period remain valid (Class IIa, IIb, III) - No design changes
Sell stock in distribution channel
Class I devices have to comply with MDR
Class IIa, IIb, III devices may comply with MDR
(after NBs are designated)
2017 2018 2019 2020 2021 2022 2023 2024 2025
Transition period
Sunset period
Year 0 Year 1 Year 2 Year 3 Year 4 Year 5 Year 6 Year 7 Year 8
Entry into Force:
2017-05-25
Date of Application:
2022-05-26
IVDMD to IVDR transitionperiod
Sell stock in distribution channel
Class A devices have to comply with IVDR
Class B, C, D devices may comply with IVDR
(after NBs are designated)