INTERNATIONAL CHECKS GROUP

EUROPEAN PHOTONICS ROADSHOW SERIES
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MEDTECH GO-TO-MARKET BARRIERS MDR2020

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EPRISE
EMPOWERING PHOTONICS

GO-TO-MARKET BARRIERS

MDR - 2020

DISTRIBUTION AND MARKET

BREXIT.. ?

CLINICAL TRIALS

FUNDS AND VCs

REGULATORY HURDLES

TAXES

INTERNATIONAL CHECKS GROUP

New way of thinking for Safety and Quality of Medical Devices

93/42 DIRECTIVE VS MDR 745/2017

MDD VS MDR

DIRECTIVES

A "directive" is a legislative act that sets out a goal that all EU countries must achieve. **However, it is up to the individual countries to devise their own laws on how to reach these goals.**

REGULATIONS

A "regulation" is a binding legislative act. It must be applied in its entirety across the EU.

MDR: 2020 – SOME NEWS

NUMBERS!

SECTION	MDR 745/2017	MDD 93/42	AIMDD 90/385
WHEREAS	101	22	12
DEFINITIONS	71	13	7
ARTICLES	123	22	17
ANNEXES	17	12	9
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MDR: 2020 – SOME NEWS

The main concepts introduced in the MDR described in more detail are:

1. **The complete overhaul of Eudamed. Introducing UDI and international nomenclature on medical devices as well as on incidents (Chapter 3 and Annex VI).**
2. **The inclusion into the scope of products without a medical purpose (Annex XVI).**
3. Supply chain regulation that obliges each entity in the supply chain to check compliance of the previous supplier. See Chapter II.
4. The introduction of a special procedure for NBs for certain high-risk devices. See Article 54.
5. The introduction of manufacturers' liability specific to medical devices and in line with the Liability Directive 85/374/EEC. Authorized Representatives will be jointly and severally liable for the devices theyrepresent. See Articles 10(16) and 11(5) respectively.
6. **The introduction of strict rules for clinical investigations and alignment to the Clinical Trials Regulation, referred to ISO 14155. See Chapter VI, Articles 62-82.**
7. The introduction of detailed rules for the execution and the results of Post-Market Surveillance and Post-Market Clinical Follow-up.
8. **Reprocessing of single-use devices is only allowed under specific conditions – permission by the member state is one of them. See Article 17.**
9. **Rules for devices produced in hospitals to be used exclusively for its own patients have been added.See Article 5(5).**
10. The rules for designation of NBs have tightened. These are provided in Chapter IV, Annex VII and Annexes IX to XII. Procedures for vigilance and post-market surveillance are described in more detail, and the fact that they have to be used for ongoing conformity assessment of the device are given indetail. See Chapter VII.

MDR: 2020 - EUDAMED

EUDAMED will be an information system for exchanging legal information related to the application of European Union Directives on medical devices between the European Commission's Enterprise and Industry Directorate General and the Competent Authorities in the European Union Member States.

Data contained within the database will include:

- Data related to registry of manufacturers, authorised representatives and devices;
- Data related to certificates issued, modified, supplemented, suspended, withdrawn or refused according to established procedures;
- Data obtained in accordance with the vigilance procedure on incidents or near-incidents which occur during the use of the medical device.

The vigilance module will report to EU Member States on incidents and near-incidents using electronic mail.
Users of the EUDAMED system will be able to load, extract and modify data, and to make reports and queries on the EUDAMED database.

MDR: 2020 - UDI

UNIQUE DEVICE IDENTIFICATION (UDI)

The Unique Device Identification (UDI) is intended to improve the traceability of medical devices throughout the supply chain by connecting all the information about each medical device through a digital information repository called Eudamed. MDR requires that a UDI label be directly attached to a medical device or to its packaging and include two identifiers:

- A UDI-DI (device identifier – linked to a manufacturer and device)
- A UDI-PI (production identifier – identifies unit of device production)

Upon production of the device, the manufacturer will have to submit the UDI-DI and additional product data (such as single registration number and whether it contains latex or other specific substances) to this central database, which will be accessible to public and healthcare professionals and provide a comprehensive overview of what medical devices are available and how they work.

MDR: 2020 - ROADMAP

Unique Device Identification (UDI) System: designation of issuing entities	recital 94 Article 27(2) MDR recital 94 Article 24(2) IVDR	Implementing Act (no comitology involved) Designation of one or more entities to operate a system for assignment of UDIs ('issuing entity').	Q2 2019	Call for application for UDI issuing entities expired on 25 January. Evaluation of applications ongoing.
EUDAMED	Article 33(8) MDR Article 30(1) IVDR	Implementing Act Definition of detailed arrangements necessary for the setting up and maintenance of Eudamed. This IA is mainly related to support, change management and maintenance rules	Q4 2019	Drafting to start by Q1 2019
EUDAMED: Implementation plan	Article 34(1) MDR	Plan for the implementation of the functional specifications for Eudamed to be drafted by the Commission.	Legal deadline for first release: 26 May 2018.	COMPLETED First release done in due time (25 May). Work in progress for further releases
EUDAMED: drawing up of functional specifications	Article 34(1) MDR	Functional specifications for Eudamed, to be drawn up by the Commission, in cooperation with the MDCG.	Q1 2019	Version 3 of high-level functional specifications were issued end of October 2018. Version 4 finalised and presented at the MDCG meeting of February 2019. It is estimated that modules for clinical investigation and market surveillance might be only partly or not at all available at the time of application of the two Regulations (due to workability issues) but few months after.
EUDAMED: Audit of functional specifications	Article 34(2) MDR	Independent audit report based on which the Commission shall inform the MDCG when it has verified that Eudamed has achieved full functionality and meets the drawn up functional specifications	Audit to start in Q3/Q4 2019. Must be finalised by Q1 2020.	First analysis of type of contract done. Contract content to be determined starting from Q1 2019 (first draft of technical annex ongoing)
EUDAMED go-live	Article 34 MDR	Eudamed may go-live from the moment a notice is published in the Official Journal of the European Union after a positive independent audit was performed that satisfies the MDCG	Notice to be published by 25 March 2020	Work in progress to elaborate functional specifications and implement them
EUDAMED: Setting of helpdesk	MDR Art 33(8)	Detailed arrangements necessary for the setting up and maintenance of Eudamed means at least the setting of an helpdesk/application support for Eudamed (normal IT good practice and implementing act obligation).	Before Eudamed go-live (March 2020)	Internal preparatory work has started.

MDR: 2020 – EU PRRC

PERSON RESPONSIBLE FOR REGULATORY COMPLIANCE

1. Manufacturers shall have available within their organisation at least one person responsible for regulatory compliance who possesses the requisite expertise in the field of medical devices.
2. Micro and small enterprises within the meaning of Commission Recommendation 2003/361/EC shall not be required to have the person responsible for regulatory compliance within their organisation but **shall have such person permanently and continuously at their disposal.**

There is no exemption for manufacturers that are only marketing low-risk devices in Europe.
All companies need a PRRC.
If you are a micro/small company (European Commission Recommendation 2003/361/EC), you can outsource this role as long as the person to whom you're outsourcing the role is qualified and **"permanently and continuously" at your disposal**.

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BREXIT…???

29 January 2019

Urgent BREXIT Implications for Market Access - 60 Days Out from 29 March 2019

The Competent Authorities advise:

a) As of 30 March 2019, the UK will *become a third country and the CE certificates will lose their validity.*

b) However, very importantly, once CE certificates lose their validity post 29 March, they will not be able to be transferred or migrated to an EU NB. Products will lose market access, and a new conformity assessment will be required.

c) Cut off for the product will be based on whether the product is considered as having been *'placed on the market'*. This is not the regulatory definition but the more traditional definition used for product recall or vigilance. *The product will be considered 'placed on the market' if before 30 March it is physically manufactured and shipped within the supply chain, for example, in a distribution warehouse (within an EU 27 member state) or the end user Hospital/Clinic etc. Product stored at the manufacturer's facility will not be deemed as having been placed on the market.*

BREXIT…ADVICE FROM BSI

1.BSI cannot mandate that you as a legal manufacturer migrate your CE certificates to our Netherlands NB, this is your own commercial decision, and we will follow your instructions into us, however, we would like you to be aware of the following view:

2.We very strongly recommend manufacturers migrate their existing BSI UK NB (0086) CE certificates to BSI NL NB (2797) as a matter of urgency.

3.Failing to complete migration of CE by 29 March creates a likelihood of interrupted market access, and as advised in 'b*' above, could lead to prolonged interruption and necessitate a full conformity assessment. BSI will take a centralized approach to the migration process to enable tracking and control.

4.Return your migration packs as soon as possible to the migration team, currently our waiting time for migration is very short but this will increase as we near the Brexit deadline. We have added additional staff to undertake this work and are diverting significant resources from other activities to ensure we complete this activity for all BSI medical devices clients urgently.

5.We understand for manufacturers with multiple CE certificates and sites you may wish to involve your Scheme Manager. If so, please ensure that initial contact is through the central process outlined to the centralized email address.

6.We will use the migration process for all active CE certificates that do not have any ongoing associated work in progress.

7.For CE certificates undergoing changes or in the 'work in progress' category we will follow the pathways outlined below:

a. For projects in pre-certification recommendation or pre-certification decision making stage (Panel) we will migrate the existing certificate to the Netherlands NB before the end of March. We will move work in progress (WIP) to the NL NB to finish and issue an amended certificate from NB 2797. This action will alleviate the need to complete this work in BSI UK NB and subsequently complete the migration by 29 March.

b. For projects already at the UK NB 0086 that have already entered the certificate decision making process (Panel), these will be fully processed and certificates issued by UK NB 0086 and then migrated to NL NB 2797 within the required timelines.

BREXIT…MDR AFTER BREXIT??

The Medical Devices Regulation (MDR) and In-Vitro Diagnostic Medical Devices Regulation (IVDR) will not yet be applicable on Brexit day. However, the transition agreement states in article 122.1: '*Union law shall be applicable to and in the United Kingdom during the transition period*.' With the Date of Application of the MDR, this implies that this EU legislation will become UK law as well. This will not work for the IVDR as that Date of Application is in 2022. However, we expect British law makers will ensure the IVDR will also be applicable.

This would result in the following situation: **The UK would become a non-EU market, not recognizing the EU Court of Justice, but British industry would manufacture medical devices and IVDs in compliance with European requirements.** Where this will lead to for the medical device industry is far from clear, but the scenario below represents the best possible outcome:

- There will be a mutual recognition agreement between the UK and the EU for medical devices and IVDs. This will enable movement of devices between both markets without the need for an Authorized Representative.
- Notified Bodies can remain in place and they will be able to issue certificates.
- The current Competent Authority in the UK, MHRA, will remain in its supervising position and will continue exchanging information with other Competent Authorities and the European Commission regarding safety and public health risks related to devices.

But this ideal solution would come at a price: UK companies will have to accept the authority of the European Court when it comes to the interpretation of the law, without any negotiating power regarding those laws. This is not what the Brexiteers had envisaged and therefore it will remain unclear exactly what will happen with medical devices after Brexit.

BREXIT…FROM MEDTECH EUROPE

Given the importance of the medical technology industry in maintaining and improving public health, there is a need for sector-specific measures during the ongoing Brexit negotiations between the EU and the UK. Such measures will not only ensure that patients continue to receive timely access to life-saving and life-changing technologies, but also ensure the future global competitiveness of an important sector for the EU economy.

To ensure that patient safety and public health across Europe and the UK are guaranteed, MedTech Europe has identified the following priorities:

1. Formal agreement on an extension of the Brexit transition period which lasts to at least 31 December 2020, taking into consideration the challenges arising from the designation of Notified Bodies during the implementation of the new In Vitro Diagnostics Regulation (IVDR) and Medical Devices Regulation (MDR) .
2. Continued authorisation in the EU27 of medical technologies CE-marked by a UK-based Notified Body, through a mutual recognition agreement.
3. Implementation of a trade agreement for healthcare to prevent development of trade barriers which would decrease industry investment capacity in innovation and industrial development.
4. A convergence of regulatory frameworks, particularly the implementation of the new IVDR and MDR for market access to both EU and UK.

DISTRIBUTION AND MARKET

TECHNOLOGY TRANSFER → ? ← DISTRIBUTION

«The transfer of technical information, tacit know-how, performance skills, technical material or equipment, jointly or as individual elements, with the intent of enabling the technological or manufacturing capacity of the recipients»

Two key determinants of effective technology transfer:

- the will to acquire new knowledge;
- collaboration and cross-pollination of ideas among diverse corporate, NGO and government stakeholders

Transfer can take place through a variety of configurations including public–private partnerships, private and institutional, and joint ventures.

Today, less than 12% of Medtech start-ups succeed to launch their product on the market. A few companies exit pre-launch, via licensing or acquire-hires, and the remainder simply runs **out of cash**. To ensure and enhance patient and clinician access to innovative, reliable and effective medical technologies, it is often necessary for medtech companies to engage third parties to assist with marketing, sales and distribution. These third parties, often referred to as distributors, may include distributors, wholesalers, distribution or sales agents, marketing agents, brokers, commercial agents and independent sales representatives.

DISTRIBUTION

Terms&conditions: Steer order, payment and after-sales service behaviour through well-defined standard terms and conditions. This is often an effective startingpoint to implement a broader distributor management improvement program. This can be done swiftly and offers the prospect of some 'quick wins'.

Distributor discount structures: Develop and use consistent national discount schemes in line with the role and performance of each sales partner. It is important **to determine whether the distributor is just a *'box mover'* – providing logistics only – or if it is a real sales partner contributing to sales, marketing, and service**. Too often manufacturers struggling with overly complex or inconsistent discount systems that lack steering and differentiation between different types ofdistributors.

International price structures: Consolidate and steer your contract and pricing activities among large international distributor groups. It is important to coordinate the price and discount structure set-up across countries to optimise the business from a global (not just a local) perspective.

Channel management: Select the most suitable distribution partners to intensify and consolidate relationships and improve the coordination between direct and indirect sales. This initiative requires a more long-term and strategic view of where the manufacturer's business is heading. The goal is to ensure that the manufacturer is pursuing its business strategy with the right partners and with an appropriate number of distributors.

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Thank you

FINISH
THANKS
FOR
YOUR
ATTENTION

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