Chubb Life Science - Medical Device Regulation

CHUBB®

The new Medical Device Regulation (MDR) will come into force on May 26 2021

In 2017, the EU adopted new Medical Device Regulation (MDR) EU 2017/745 to make the introduction of medical devices into the EU market safer.

After a transition period of 3 years, the regulation should be fully in force. The outbreak of the COVID-19 pandemic necessitated a delay of one year.

But now the time has come. On May 26 2021, the MDR will apply in the European Economic Area as the legal basis for medical device manufacturing.

Main Changes

- Manufacturer obligations:
  - Risk Management System for each device
  - Clinical evaluation for all devices
  - Product conformity procedure (CE approval)
  - Quality management
  - Sufficient financial coverage
  - Qualified person
- UDI (Unique Device Identification system) traceability to end-user
- Notified Bodies assessing medical devices for CE market: now Notified Bodies certified and controlled by new national authority
- Clinical trials for Class III products
- EUDAMED (European Data Bank for Medical Devices)
  - access to the public
  - brought information of all devices
- Software for health technology is considered a medical device
- Market surveillance monitoring system must be introduced by the manufacturer

What happened so far

Over the past 12 months, the Medical Device industry has been at the epicentre of the COVID-19 crisis. One of the most urgent tasks was to maintain the supply chains and thus secure patient care.

Nevertheless the following steps have been achieved:

- 18 notified bodies approved, expect 36 (coming from over 50)*
- GAP analysis: this is the first step in identifying missing or incomplete MDR compliance of all devices from the former Medical Directive
- UDI Unique Device Identifier in progress

The deadline for assigning UDIs is the respective Day of Application (DoA) . However, the obligation to affix the UDI on the labelling will be implemented in three stages for Medical Devices. The UDI should be affixed at the latest by:

1. Class III devices: 26 May 2021
2. Class II devices: 26 May 2023
3. Class I devices: 26 May 2025

* As of 17th of February 2021

Insurer / Support

Insurance matter
MDR 2017/745 Article 10.16

"... Manufacturers shall... have measures in place to provide sufficient financial coverage in respect of their potential liability under Directive..."

MDR does not, however, specify what is meant by "sufficient", other than that it should be proportionate to the risk profile of the device.

How can Chubb support you?
Services we can provide:

- The insurer together with broker and client should evaluate the exposure based on:
  - Risk class
  - Turnover
  - Claim scenarios: most likely vs highest possible damage

At the end it remains the responsibility of the insured to make a decision in collaboration with the broker on limit adequacy based on this analysis.

Obligations for medical device manufacturers with non-EU residence

Authorised Representative: Manufacturers with a registered office outside the European Union already had to appoint an authorised representative in the EU according to the Medical Directive 93/42/EEC, Article 14.

The role of the Authorised Representative is continued in the MDR (EU) 2017/745 in Article 11 and is attended to with detailed tasks. From an insurance perspective, these extended tasks lead to complicated and unsatisfactory solutions, which make the security desired by the legislator extremely difficult.

Authorised Representative shall have a person at their site who has to have an academic or comparable education in law, medicine, pharmacy, engineering or another relevant scientific discipline. In doing so, the legislature wants to ensure that the Authorised Representative has expertise available to handle the various new responsibilities.

MDR and Switzerland

Importing from the EU to Switzerland and exporting from Switzerland to the EU could become problematic as the Mutual Recognition Agreement (MRA) is not signed off by Switzerland.

Background; The new European Union regulation comes into force in May. From May, medical products will have to obtain a new certificate before they can be sold. Switzerland has introduced these certificates, however the EU has refused to recognise them historically as Switzerland had not signed the finished Mutual Recognition Agreement.

The remaining timeframe for ratification of the Mutual Recognition Agreement is limited to May 26 2021.

Without recognition of the Mutual Recognition Agreement, there could be shortages of medical devices in Switzerland.

Non-EU manufacturers and exports into the European Union

Manufacturers not located in the EU

According to MDR Article 11 a sole Authorised Representative is required in the EU. Main responisbilities are:

- Verification of the existence of declaration of conformity and technical documentations
- If required by authorities, submission of these documents
- If required, forwarding of samples or access to product documents to all EU countries
- Cooperation with authorities regarding preventive or corrective measures
- Immediate information to the manufacturer regarding incidents with the medical device

Article 11 point 5: Liability of the Authorised Representative (AR)

Without prejudice to paragraph 4 of this Article, where the manufacturer is not established in a Member State and has not complied with the obligations laid down in Article 10, the authorised representative shall be legally liable for defective devices on the same basis as, and jointly and severally with, the manufacturer.

Insurer / Support

Insurance of the Authorised Representative

The responsibility the Article places on the AR and a professional liability policy is rarely appropriate. The fact that the Article places responsibility jointly and severally liability with the manufacturer, the AR accepts a risk that is not in balance with the fee paid for service. Furthermore the insurer is not in the position to evaluate the product risk and the quality controls of the manufacturer.

The recommended course of action is that the AR is named as additional insured for the product risk on the policy of the manufacturer (and retains documentation to evidence this).

Switzerland
If the MRA is not signed off by 26 May 2021 an Authorised Representative will have to be established for Swiss companies exporting into the EU and vice versa for European manufacturers exporting to Switzerland.

How BREXIT affects medical devices

The latest MDR legislation in Europe and regulatory reform by the FDA have left many companies unsure about how to pursue the best regulatory pathway.

Chubb's UK branch can continue to provide a policy solution that will provide continuous and uninterrupted service whilst maintaining S&P AA rating.

Chubb will be authorised by the PRA while also remaining part of the same legal entity Chubb European Group SE. This will allow UK underwriters to underwrite risks located in the EU on the basis that they are underwriting on behalf of Chubb European Group SE, an insurer authorised in the EU.

Chubb Underwriters in the EU will also be able to underwrite risks located in the UK on the basis that Chubb European Group SE has an authorised branch in the UK.

Exporting to European Union

Entities domiciled in Great Britain
- Comply with EU MDR
- Class I medical devices and general IVDs can continue to self-declare conformity self-declared against the EU MDD or EU IVD
- The European Authorised Representatives (EARs) based out of the UK will no longer be recognised by the EU and the manufacturers shall appoint a new EAR
- CE marking
- To move goods into or out of the EU an EORI number is required
- Check the new rules for parallel exporting IP protected goods from the UK to the EU

Entities domiciled in Northern Ireland
- Comply with EU MDR
- Conformity Assessment by Notified Body (EEA)
- CE

Entities domiciled in European Union
- Comply with EU MDR
- Conformity Assessment by Notified Body (EEA)
- CE marking

Exporting to Great Britain

Entities domiciled in Great Britain
- All devices, irrespective of device class, must be registered with the MHRA
- Compliance with;
  - UK MDR 2002,
  - EU MDR (until 30 June 2023)
- Unique reference codes
- UKCA marking
- Class I medical devices and general IVDs can continue to self-declare conformity self-declared against the EU MDD or EU IVD

Entities domiciled in Northern Ireland
- Non-UK medical device manufacturers need to appoint a UK Responsible Person (UKRP), who must register with the MHRA
- Device registration with MHRA
- Compliance with;
  - UK MDR 2002
  - EU MDR (until 30 June 2023)
- UKCA or CE UK (NI) marking

Entities domiciled in European Union
- Non-UK medical device manufacturers need to appoint a UK Responsible Person (UKRP), who must register with the MHRA
- UKRP and device registration with MHRA
- UKCA marking

* CE marking will be recognised until 30 June 2023

Exporting to Northern Ireland

Entities domiciled in Great Britain
- Comply with EU MDR
- Class I medical devices and general IVDs can continue to self-declare conformity self-declared against the EU MDD or EU IVD
- The European Authorised Representatives (EARs) based out of the UK will no longer be recognised by the EU and the manufacturers shall appoint a new EAR
- CE or CE UK (NI) marking

Entities domiciled in Northern Ireland
- Comply with EU MDR
- Conformity Assessment by Notified Body (EEA)
- Manufacture and Device registration with MHRA
- CE or CE UK (NI) marking

Entities domiciled in European Union
- Comply with EU MDR
- Conformity Assessment by Notified Body (EEA)
- Manufacture and Device registration with MHRA
- CE or CE UK (NI) marking

Contact us

Chubb European Group
100 Leadenhall Street
London
EC3A 3BP

T: 020 7173 7000
F: 020 7173 7800

www.chubb.com/uk

Chubb. Insured.[SM]

UK7977-MD 04/21