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New Medical Devices Ordinance effective from 26 May 2021 - Need for action in the Medtech sector

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May 26, 2021 was the effective date of the Medical Devices Regulation (MDR) and the revised Swiss Medical Devices Ordinance (MedDO) came into force. All stakeholders are aware that the Mutual Recognition Agreement (MRA) between Switzerland and the European Union (EU) could not be updated by May 26, 2021. As a result, Switzerland has become a "third country" in the area of medical devices as of May 26, 2021.

Swiss Manufacturers

1. Introduction

Up to now, Switzerland has been able to participate in the EU common market for medical devices (classic and active implantable) without any restrictions. This was ensured for products that were placed on the market in accordance with the two EU directives (MDD, 93/42 EEC and AIMDD, 90/385/EEC). They are listed in the Agreement between the Swiss Confederation and the European Union on Mutual Recognition in relation to Conformity Assessment (MRA). Since the Institutional Agreement (InstA, Framework Agreement) between Switzerland and the EU was not approved and therefore the MRA could not be updated, one of the consequences is that Swiss manufacturers will have to comply with third country requirements for devices they place on the market in accordance with the requirements of the EU Medical Device Regulation (Regulation (EU) 2017/745 - Medical Device Regulation, MDR) from the date of application. This includes all products from the date of application in accordance with the MDR, as well as products placed on the market on the basis of certification in accordance with the MDD and AIMDD. This is because, as of the date of application, old certified products (MDD and AIMDD) are also considered to be subject to the MDR. Swiss manufacturers must appoint an authorized representative in the EU or EEA and adapt the labeling of their products accordingly. The authorized representative represents the manufacturer in the EU area and assumes certain manufacturer responsibilities and risks. For this purpose, the representative must also have access to the technical documentation, among other things. The authorized representative can be chosen freely. He must fulfill certain conditions regarding regulatory know-how and be located in the EU/EEA area. In addition to service providers, an importer, a distributor or a subsidiary can also act as an authorized representative.

2. Authorized Representative

Swiss manufacturers must appoint an authorized representative with a place of business within the EU or EEA to place products on the market in compliance with the MDR. The authorized representative must be indicated accordingly on the label before the products can be placed on the market in the EU. Authorized representatives based in Switzerland who were able to represent non-European manufacturers with their products until the MDR came into force can no longer pursue these activities.

2.1. Products

From the start of validity, products for which a valid certificate (MDD or AIMDD certificate) is still available as well as MDR products are concerned

2.2. Designation

An authorized representative is *any natural or legal person established within the Union who has received and accepted a written mandate from a manufacturer, located outside the Union, to act on the manufacturer's behalf in relation to specified tasks with regard to the latter's obligations under this Regulation* (Art. 2 Section 32 MDR). In principle, there are no restrictions on the choice of an authorized representative. It is therefore possible for the Swiss manufacturer to designate an importer or distributor. Authorized representatives must be designated for all products placed on the market in compliance with the MDR. A manufacturer may designate different authorized representatives for different products. However, individual authorized representatives must be designated at least for all products of a generic product group (according to Art. 2 Section 7 MDR). Furthermore, it must be specified that the tasks of an authorized representative are performed independently of the residual interests of an importer/distributor. Alternatively, a subsidiary of a manufacturer, which has its registered office in the EU or the EEA, can also be designated as an authorized representative. The exact tasks of the authorized representative must be defined in a mandate. This mandate is only valid if accepted in writing by the authorized representative. The authorized representative is also required to provide the competent foreign authority with a copy of the mandate agreement upon request.

2.3. Requirements

An authorized representative who has been appointed for products authorized under the MDR must have permanent and continuous access to a professional in the EU/EEA area who is demonstrably responsible for compliance with the regulatory requirements for medical devices in the mentioned area. This person must be resident in the EU/EEA area. The proof of expertise can be provided as follows: *a diploma, certificate or other evidence of formal qualification, awarded on completion of a university degree or of a course of study recognized as equivalent by the Member State concerned, in law, medicine, pharmacy, engineering or another relevant scientific discipline, and at least one year of professional experience in regulatory affairs or in quality management systems relating to medical devices* (Art. 15 Para. 6 MDR).

The recourse of an authorized representative to a specialist must be ensured on a permanent basis. The authorized representative must register in EUDAMED, the European Database for Medical Devices, and is assigned an identification number by the competent authority.

2.4. Tasks

The authorized representative becomes the primary contact person for the competent authorities in the EU or EEA. The minimum duties of an authorized representative are defined in Art. 11 MDR and can be divided into the following areas:

- Verifying compliance with registration requirements
- Keeping the documentation available
- Supporting the authorities during audits and product inspections
- Reporting of incidents and complaints (Vigilance Report)

Pursuant to Art. 11(4) MDR, the following duties of the manufacturer may not be delegated to the authorized representative:

- Ensuring the conformity of the products
- Maintaining a risk management system
- Performing clinical evaluations
- Writing and updating the technical documentation
- Preparation of the Declaration of Conformity
- Maintaining the UDI database

- Maintaining the manufacturer's quality management system
- Establish post-market surveillance system
- Creating the labeling and instructions for use
- Determining necessary corrective actions

2.5. Liability

If the manufacturer does not fulfill his obligations according to the MDR, authorized representatives are jointly and severally liable with the manufacturer for defective products. This extended liability carries a risk for the authorized representative because he has no direct control over the conformity of the products. He may neither be entrusted with measures to ensure product conformity, nor may he modify non-conforming products himself. On the other hand, the authorized representative is obliged to terminate his mandate if the manufacturer violates his obligations under the MDR. In such event, the authorized representative must notify the competent authorities (and, if applicable, the competent body for the withdrawal of the mandate), stating the reasons. Liability issues must be settled between the manufacturer and the authorized representative, also for the time after the mandate has ended. Finally, the extended liability of an authorized representative places high demands on insurance coverage.

2.6. Requirements for the Manufacturer

The manufacturer must provide the authorized representative with all necessary documents. This may also include confidential information if required for registration or product testing. Furthermore, the labeling of the products must be adapted, as it must clearly identify the authorized representative. Finally, the name and address as well as the registered identification number of the authorized representative must be indicated on the declaration of conformity. The name and address of the authorized representative must also be indicated on a certificate of conformity.

2.7. Change

In principle, there is nothing to prevent a change of authorized representative. The arrangements for a change must be regulated in an agreement between the manufacturer and the previous and future authorized representatives. At least the following points must be clarified:

- Time of termination and recommencement of the mandate.
- The date until which the previous authorized representative may be named in the information provided by the manufacturer, including promotional materials.
- Handover of documents and regulation of confidential aspects and property rights.
- Obligation of the previous authorized representative to continue to forward to the manufacturer or the new representative all reports of incidents in connection with products for which he was responsible, even after termination of the mandate.

2.8. Deadlines

From May 26, 2021, third country requirements will apply to Swiss manufacturers, as the MRA could not be updated.

3. Conclusion

Products from Swiss manufacturers that are placed on the EU market in accordance with the regulatory basis to be complied with from the date of application of the MDR are not within the scope of the MRA, as amended on December 22, 2017. Consequently, all such products from Swiss manufacturers have to comply with the requirements for a third country. This includes, among other things, the designation of an authorized representative. Authorized representatives domiciled in the EU or EEA can be held legally responsible locally. The primary purpose of the authorized representative is to verify and ensure that, at the latest from the date of application, the manufacturer complies with his obligations set out in the MDR. Since the authorized representative can also be held jointly liable for product defects, it is in his interest to perform this task conscientiously. In addition, the authorized representative must terminate his mandate - as soon as the manufacturer fails to

meet his obligations - and must also report this to the authorities, giving reasons for the termination. Therefore, special attention should be paid to the choice of the authorized representative. Candidates for this are distributors/importers, service providers or even the company's own subsidiary.

Swiss Distributors and Importers

1. Introduction

The European Medical Devices Regulation (MDR) entered into force simultaneously with the corresponding Swiss Medical Devices Regulation (MedDO). Switzerland and the European Union (EU) have not been able to agree on an update to the Mutual Recognition Agreement (MRA) or on a transitional solution under which the current MRA would continue to apply. As a result, all Swiss distributors of medical devices must comply with new legal requirements, as Switzerland is no longer part of the European Single Market for medical devices. The revised MedDO, equivalent to the MDR, uses the concept of Swiss Authorized Representatives, which are mandatory for all manufacturers (in the sense of a "legal manufacturer") outside of Switzerland to place medical devices on the Swiss market. Since the MRA could not be updated, the role of Swiss authorized representatives can no longer be fulfilled by a European company (manufacturer or European authorized representative) as was previously the case. The first version of the revised MedDO was prepared with a fully functional MRA in mind. Its implementation was not possible without an updated MRA. Therefore, supplementary provisions were adopted. These entered into force simultaneously with the totally revised MedDO on May 26, 2021.

2. Swiss Authorized Representative

According to Art. 51 of the revised MedDO, any manufacturer not domiciled in Switzerland may only place its products on the Swiss market if he has authorized a person domiciled in Switzerland. The provisions mentioned in the MedDO regarding a Swiss authorized representative correspond to those of the MDR for a European authorized representative. These provisions are already set out above under the heading **Swiss Manufacturer**.

2.1. Designation

The MedDO defines an authorized representative as *any natural or legal person established in Switzerland who is mandated in writing by a manufacturer established abroad to perform certain tasks on his behalf in fulfillment of the manufacturer's obligations arising from this ordinance* (Art. 4 para. 1 lit. g MedDO). A Swiss authorized representative must be appointed for all products of a generic product group of a manufacturer. Swiss authorized representatives must receive a unique registration number and be registered with Swissmedic.

2.2. Tasks and Obligations

The Swiss authorized representative must have permanent and permanent recourse to at least one person who is responsible for compliance. The responsibility of this person as well as exceptions and further modalities are governed by Article 15 MDR. The responsibilities of a Swiss Authorized Representative are essentially the same as those of an EU Authorized Representative and include:

- Verifying compliance with registration requirements
- Guaranteed access to the technical documentation
- Cooperating with authorities on corrective actions and product testing
- Reporting incidents and complaints

Some of the manufacturer's obligations may not be delegated to a Swiss authorized representative:

- Ensuring product conformity
- Maintaining a risk management system
- Performing clinical evaluations
- Writing and updating technical documentation
- Preparing the Declaration of Conformity
- Maintaining the UDI product identification number database

- Maintaining the manufacturer's quality management system
- Establishing post-market control system
- Preparation of labeling and instructions for use
- Definition of necessary corrective actions

In accordance with the EU Authorized Representative, Swiss Authorized Representatives are legally liable with the manufacturer as joint and several debtors for defective products if the manufacturer does not fulfill his obligations according to the MedDO. These are required to have adequate financial coverage for damages caused by defective medical devices.

2.3. Change

If a manufacturer wishes to change its Swiss authorized representative, the detailed arrangements must be clearly set out in an agreement between the manufacturer, the previous authorized representative and the new one.

3. Failure to update the MRA

On May 19, 2021, the Federal Council adopted the amending decree of the totally revised MedDO. The date of entry into force was set to be May 26, 2021. The decree provides for transition periods. With the amendments adopted by the Federal Council, the equivalence of the Swiss provisions to those of the EU is maintained, which means that a subsequent update of the MRA remains possible.

4. Important contents of the amending decree

- The amendment to the MedDO provides for transition periods varying according to risk classes for the designation of a Swiss authorized representative, including corresponding labeling.
- Registration and notification obligations do not run via EUDAMED, but via Swissmedic. Economic operators who have already placed products on the market according to the MDR before May 26, 2021, must complete the registrations by November 26, 2021.
- Access to the technical documentation can be provided by keeping a copy available at the authorized representative or by a contractually guaranteed assurance that delivery will be made within seven days upon request by Swissmedic.

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