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Online event

Information on the new medical devices regulation

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Requirements for healthcare institutions

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Relevant information on legal requirements

- **Therapeutic Products Act (TPA):** www.fedlex.admin.ch/eli/cc/2001/422/en
- **Medical Devices Ordinance (MedDO):** www.fedlex.admin.ch/eli/cc/2020/552/en
- **MDR:** https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R0745
- **Swissmedic website:**
  - Gen. MD: www.swissmedic.ch/swissmedic/en/home/medical-devices.html
  - Monitoring of healthcare institutions: https://www.swissmedic.ch/swissmedic/en/home/medical-devices/reprocessing---maintenance.html#1892001807
- **Industry associations, professional associations**

Monitoring of healthcare institutions 1/2

- **Art. 76 Responsibilities**

  [1]**Swissmedic** is responsible for monitoring:

  a. devices and device conformity;

  b. **vigilance**;

  c. **maintenance** and **reprocessing** of devices,
  that are intended for **use in hospitals**.

  [3]The **cantons** are responsible for monitoring:

  a. …;

  b. …;

  c. the **maintenance and reprocessing of devices**
  by the **professionals using them** and in
  healthcare institutions with the exception of hospitals.

Surveillance of healthcare institutions 2/2

Note

→ **Third-party companies that reprocess or maintain medical devices are now also subject to monitoring by Swissmedic**

Definition of hospital

- **Art. 4 Further definitions**

  [1]In this Ordinance:

  …

  k. ***healthcare facility*** means any organisation whose primary purpose is to provide care or **treatment** for **patients** or to **promote public health**;

  l. ***hospital*** means any healthcare institution in which **inpatient treatments** for illnesses, **inpatient** medical rehabilitation and **inpatient** medical measures for cosmetic purposes are provided by medical or nursing interventions;

Definition of hospital

Note

→ Special clinics with inpatient measures, e.g. beauty clinics, are subject to **monitoring by Swissmedic**

→ Outpatient clinics, practices and affiliates of a clinical group are subject to **monitoring by cantons**

Definition of maintenance and reprocessing 1/2

- **Art. 4 Further definitions**

  [1]In this Ordinance:

  …

  d. ***maintenance*** means measures such as mechanical maintenance, software updates, inspection, repair, **preparation for first use** and **reprocessing for reuse** or measures to keep a device in functional condition or restore it to functional condition;

  e. ***reprocessing*** means a process **carried out on a used device** in order to allow its safe reuse, including **cleaning, disinfection, sterilisation and related procedures**, particularly **packaging, transport and storage, as well as testing and restoring the technical and functional safety of the used device**;

Definition of maintenance and reprocessing 2/2

Note

→ **"Reprocessing" continues to be part of maintenance**

→ **Vagueness:** According to MDR, "reprocessing" only refers to a process carried out on "used devices"

→ The first or one-off reprocessing (e.g. non-sterile implants) is covered by the term "maintenance" ("preparation for first use")

→ **"Reprocessing" covers all stages that a used device undergoes until it can be reused in a safe and compliant manner** (incl. transport, precleaning, functional testing, packaging, storage, etc.)

Maintenance: Obligations of healthcare institutions 1/3

- **Art. 71 Maintenance**

  [1]Any person using devices in a professional capacity must ensure that the devices are maintained […] in accordance with the regulations.

  [2]Maintenance must be carried out in accordance with the principles of a **quality management system,** is to be organised **and documented** appropriately, and must be guided in particular by:

  a. the **manufacturer's instructions**;

  b. the particular **risk** associated with the device […].

  [4]**Swissmedic can issue and publish requirements for maintenance measures**. These requirements will be deemed to constitute the **current scientific and technological standards**.

Maintenance: Obligations of healthcare institutions 2/3

Procurement & inventory: EU conformity and changes in the classification of MD

- Verification of the validity dates of EU certificates (Art. 120 para. 2, 3 MDR)
  →**Certificates issued according to the MDD remain valid until 26.05.2024 at the latest**
  →Alternative strategies for medical devices that are not newly certified according to MDR
  → See Swissmedic information sheet on procurement at https://www.swissmedic.ch/swissmedic/en/home/medical-devices/reprocessing---maintenance/beschaffung.html
- Were medical devices assigned to a higher class by MDR?
  → e.g. reusable instruments in the new class Ir (r=reusable)
  → software as a medical device, from class I to IIa
  → other devices, e.g. from IIb to III
  → **Transitional period for placing on the market until 26.05.2024** (see Art. 120 para. 3)
- For medical devices assigned to a higher risk category according to MDR
  → impact on prioritisation in maintenance planning

Maintenance: Obligations of healthcare institutions 3/3

- **Art. 74 Cyber security**

  [1]**Healthcare institutions** must put in place **all technical and organisational resources required by the state of the art** to ensure that network-compatible products are **protected against electronic attack and unauthorised access**.

  [2] **Hospitals** must identify, evaluate and document the measures taken under paragraph 1 in accordance with the principles of a **risk management system**. **This system forms an integral part of the hospitals' quality management system**.

- Requirements relating to risk management in information security for hospitals:
  → Does an information security management system (ISMS) according to **SN ISO/IEC 27001** exist?
  → Does a risk management process for IT networks incorporating medical devices according to **SN EN 80001** exist?

Modification: Obligations of healthcare institutions 1/2

- The modification of devices may be part of maintenance measures
- The modification of medical devices is regulated in the EU-MDR

- **Art. 16 para. 1 EU-MDR**
  [1]A distributor, importer or other **natural or legal person shall assume the obligations incumbent on manufacturers** if it does any of the following:
- …
  b. **changes the intended purpose** of a device already placed on the market or put into service;
  c. **modifies** a device already placed on the market or put into service in such a way that **compliance** with the applicable requirements **may be affected**

Modification: Obligations of healthcare institutions 2/2

- **Art. 23 para. 2 EU-MDR**

  [2]An item that is intended specifically to replace a part or component of a device and that **significantly changes the performance or safety characteristics or the intended purpose of the device shall be considered to be a device and shall meet the requirements laid down in this Regulation**.

Note

If maintenance affects the intended purpose or conformity, the following applies:
Any natural or legal person who modifies a device such that the intended purpose or the performance or safety characteristics of the device is changed **must meet the requirements of a manufacturer**
→ Technical documentation, conformity assessment procedures, certification, etc.
→ Modification amounts to manufacture

But: Limited requirements can apply to healthcare institutions
→ **Art. 9 MedDO Devices manufactured and used in healthcare institutions**

Manufacture: Obligations of healthcare institutions 1/2

- **Art. 9 Devices manufactured and used in healthcare institutions**

  [1]Devices manufactured and used solely within healthcare institutions are deemed to have been put into service. **Such devices are subject to the pertinent general safety and performance requirements of Annex I EU-MDR**, but not to any of the other requirements set out in this Ordinance, provided the requirements of **Article 5 paragraph 5 letters a–h EU-MDR** are fulfilled

- **Art. 18 Obligation to report the use of devices manufactured in healthcare institutions**

  [1]Healthcare institutions that manufacture and use devices as specified in Article 9 **shall provide the following information to Swissmedic prior to putting the devices into service:**

  a. their name and address;

  b. the name and intended purpose of the device;

  c. the risk class of the device in accordance with Article 15 paragraph 1.

Manufacture: Obligations of healthcare institutions 2/2

Note

→ Medical devices manufactured and used in healthcare institutions only need to satisfy the **general safety and performance requirements of Annex I EU-MDR provided that certain conditions are met (see Art. 5 para. 5 EU-MDR), e.g.**

- The devices are not transferred to third parties
- Appropriate QMS for manufacture and use,
- No equivalent device on the market,
- Documentation showing that general safety and performance requirements of Annex I EU-MDR are satisfied, etc.

→ The devices must be reported to Swissmedic before they are put into service

→ These devices may not be CE-marked (Art. 13 para. 2 MedDO)

→ The same requirements apply to modified devices

Reprocessing: Obligations of healthcare institutions 1/5

- **Art. 72 Reprocessing:**

  [1] Any person using, in a professional capacity, a device intended for repeated use must ensure […] that its functionality has been tested and that it has been processed in accordance with **current scientific and technological standards** and **taking account of the instructions of the manufacturer** and the requirements of **hygiene**.

  [2] Reprocessing must employ suitable **procedures** that have been **validated in accordance with current scientific and technological standards** and whose efficacy has been demonstrated and can be reliably traced and reproduced within a **quality management system**.

Reprocessing: Obligations of healthcare institutions 2/5

- **Art. 72 Reprocessing:**

[3] Any natural or legal person who processes devices for third parties must:

a. declare that the […] device

1. has been processed in accordance with the **manufacturer's instructions**, or

2. has been processed using a procedure specific to the processor that is **equally safe and effective** as the procedure specified by the manufacturer, and has been demonstrated to be equally safe and effective by means of a **risk analysis** and **validation process**;

b. operate a **quality management system** that is both suitable and **certified** to nationally or internationally recognised standards;

c. provide proof that reprocessing takes place in **suitable premises,** in accordance with the recognised rules of **science and technology** and in compliance with **hygiene requirements**;

Reprocessing: Obligations of healthcare institutions 3/5

Note

→ Reprocessing should be organised, carried out and documented within the framework of a **QMS**

→ Reprocessing should be carried out in accordance with **current scientific and technological standards** taking account of the **instructions of the manufacturer**. The hygiene requirements should be taken into account
(e.g. appropriately trained professionals, modern infrastructure such as the physical separation of dirty and clean zones in the CSSD or endoscopy department, avoidance of cross-contamination by correct routing, appropriate hygiene plans, etc.)

→ **The whole reprocessing process should be validated (not just washer/disinfector and sterilisation procedures)!**

→ **These obligations basically apply not only to hospitals, but also to all affected healthcare institutions / professionals!**

Reprocessing: Obligations of healthcare institutions 4/5

Note

→ Companies or healthcare institutions that reprocess for third parties

- require a certified QMS
- must, if they deviate from the manufacturer's instructions, prove that the reprocessing process used is equally effective and safe → **risk analysis, validation**
- must prove that they reprocess in **suitable premises** in accordance with **current scientific and technological standards** and satisfy the **hygiene requirements**

Reprocessing: Obligations of healthcare institutions 5/5

- **Art. 73 Single-use devices and their reprocessing**

  [1] **Reprocessing and further use of single-use devices is forbidden.**

  [2] **Single-use devices reprocessed in a foreign country […] must neither be used nor made available on the market.**

Note

→ Single-use devices must on no account figure in the reprocessing process of the CSSD/Med. Dev. Reprocessing Unit!

Further obligations of healthcare institutions 1/3

Implantation certificate:

- **Art. 20 Information on implantable devices**
  For implantable products, the **manufacturer** must provide, in addition to the product information required under Article 16, the **information required under Article 18 paragraph 1 EU-MDR**, including the **implantation certificate**. The exemptions specified under Article 18 paragraph 3 EU-MDR apply, taking account of the amendments adopted by the European Commission by means of delegated acts.

  The implantation certificate must be written in all three official languages of Switzerland.

  [3] **Healthcare institutions must enter the details of the implant recipient in the implantation certificate and give the certificate to the recipient.** They provide the essential information needed by the recipient in a quickly accessible form.

Further obligations of healthcare institutions 2/3

Note

→ The **implantation certificate** is provided by the manufacturer for implantable devices and includes the information needed to identify the device, including the **device name, serial number, lot number, the UDI, the device model, as well as the name, address and the website of the manufacturer**

→ The following implants are exempted from the obligations laid down in Art. 20 MedDO and Art. 18 para. 1 EU-MDR: **sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, dental and bone plates, wires, pins, clips and connectors.**

→ **Healthcare institutions** give the completed implantation certificate to the person that has received the implant.

Further obligations of healthcare institutions 3/3

Recording the UDI:

- **Art. 65 Recording the UDI**

  [1] Economic operators and healthcare institutions shall store and keep, preferably by electronic means, the **UDI of the class III implantable devices** which they have supplied or with which they have been supplied.

  [2] Swissmedic may extend this obligation to other devices, or categories or groups of devices.

- The UDI is a standardised, coded sequence of numeric or alphanumeric characters
- **It allows unambiguous identification of specific devices on the market**
- Before a medical device is placed on the market, the manufacturer must assign a unique device identification (UDI) to the device (affixed to the device label and packaging).
- The UDI is issued in a phased manner according to the transitional periods defined in the MDR
- For further information see the Vigilance section of the Swissmedic website: https://www.swissmedic.ch/swissmedic/en/home/medical-devices/reporting-incidents---fscas.html

Recommendations and expectations for hospitals

During hospital inspections Swissmedic has noticed that a number of hospitals:

- are unaware, or insufficiently aware, of the implications of the new MedDO (or MDR)
- overtaxed with the situation or have reacted too late

Recommendations

- Form a Task Force with the affected departments (e.g. CSSD, Endoscopy, QM managers, Vigilance, Medical Technology, Medical Informatics, IT, Purchasing, doctors, operating theatres, etc.)
- Define responsibilities, interfaces and required resources (incl. external specialists)
- Carry out gap analysis (actual vs. target situation) and risk analysis based on the MedDO and MDR, define measures with deadlines (depending on urgency),
- Update the overriding quality management system/information security management system or implement with standardised process and document structure (if nec. arrange for system to be certified)
- Regular progress reports for the attention of the management

Thank you for your valued attention