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Online event

Information on the new medical devices regulation

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Manufacturers

Obligations of economic operators in Switzerland
Revised Medical Devices Ordinance

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Disclaimer

- *The applicable medical device provisions of the Therapeutic Products Act (TPA; SR 812.21) and the Medical Devices Ordinance (MedDO; SR 812.213) have been generalised for this presentation.*
- *The current legal provisions apply in all cases.*
- *Specific cases are not covered by this presentation.*

Manufacturer

any natural or legal person who

- manufactures a device or
- fully refurbishes a device or
- has a device designed, manufactured or fully refurbished and
- markets that device under its name or trademark;

- *Definitions: Art. 4 para. 1 let. f MedDO*

Obligations of manufacturers - Overview I

General obligations of manufacturers:

- Obligations according to Art. 50 MedDO in conjunction with Art. 10 MDR, particularly:
  - Risk management system
  - Quality management system
  - Conformity assessment procedure
  - Product information (labelling and instructions for use)
- Conduct clinical evaluations (Art. 46 MedDO)
- Keep technical documentation (Art. 47 MedDO)
- Conformity marking (Art. 46 MedDO)
- Appoint a Person Responsible for Regulatory Compliance (PRRC) (Art. 49 MedDO)
- Obligations to archive (Art. 48 MedDO)

- Foreign manufacturers: Appoint an authorised representative (CH-Rep) (Art. 51 MedDO)

Obligations of manufacturers - Overview II

- Registration with Swissmedic (Art. 55 MedDO):
  - incl. details of the PRRC
- Device identification (UDI) (Art. 17 MedDO)
  - Assign and place the UDI on device & device registration
- Implant card in the three official languages (Art. 20 MedDO)

- **Device surveillance (Chapter 7 MedDO)**
  - Post-market surveillance (Art. 56 - 59 MedDO)
  - Prepare and update a safety report (Art. 60 MedDO)
  - Summary of safety and clinical performance (Art. 63 MedDO)
  - Traceability and device identification
    - Traceability (Art. 64 MedDO)
    - Duty of disclosure under Art. 47c TPA
  - Vigilance system (Art. 66 MedDO)

> applicability to devices that comply with the old legislation, see Art. 101 para. 2 MedDO

Assumption of obligations incumbent on manufacturers – Art. 16 para. 1 MDR

Distributor, importer or other **natural or legal person shall assume the obligations incumbent on manufacturers** if it:

- makes a device available on the market
  - under its own name,
  - with its own registered trade name or
  - with its own registered trademark

  subject to an agreement between manufacturer, distributor and/or importer.
  - This means the manufacturer can affix specific presentations and brand names provided all requirements are met
  - In all cases, the manufacturer should be stated on the labelling.

- **changes to the intended purpose** of devices already placed on the market or put into service

- change to a device already placed on the market or put into service, **with possible implications for its conformity**

acc. to definition of a manufacturer, Art. 4 para. 1 let. f in conjunction with Art. 16 para. 1 MDR

Systems and procedure packs (Art. 11 para. 3 MedDO)

- Persons who put together "regular" systems / procedure packs according to Art. 22 para. 1 MDR are **not** manufacturers as defined in Art. 4 para. 1 let. f MedDO

- **Assumption of obligations as a manufacturer according to Art. 46-50 MedDO** for systems and procedure packs that:
  - contain devices without a conformity marking
  - involve a combination of devices that is not compatible with the original intended purpose, or
  - were not sterilised according to the manufacturer's instructions

- Additionally, conduct a conformity assessment procedure according to Art. 23 MedDO

- Example:
  EO-sterilised procedure pack with devices that were designed by the manufacturer for sterilisation using moist heat

Manufacturers of custom-made devices – Art. 10 MedDO

- Manufacturers of custom-made devices are deemed to be manufacturers as defined in the MedDO

- specific requirements and obligations apply:
  - Requirements according to Annex XIII MDR
  - Statement according to Annex XIII Section 1 MDR
  - Additionally for class III custom-made devices:
    - Conformity assessment procedure according to Annex IX MDR
    - Alternatively, conformity assessment procedure acc. to Annex XI Part A MDR
  - Documentation according to Annex XIII Section 2 MDR

- Typical examples:
  - Individually manufactured implant for a specific patient
  - Tooth replacement in dentistry
  - Orthoses

Conformity assessment

- "Any person […] who places a device on the market […] must […] carry out and be able to produce documentary evidence of an evaluation of the device's conformity with the general safety and performance requirements".

- *Basis* *Art. 21 para. 2 MedDO*

Conformity assessment

- "A medical device used in accordance with its intended use must not endanger the health of the user, the consumer, the patient or a third party. The intended performance must be demonstrated." Art. 45 para. 1 TPA

- "Any person placing a **medical device** on the market must be able to prove that the device satisfies the fundamental requirements..", Art. 45 para. 2 TPA

- "…must, before placing it on the market, carry out and be able to produce documentary evidence of an evaluation of the device's conformity with the general safety and performance requirements", Art. 21 para. 2 MedDO

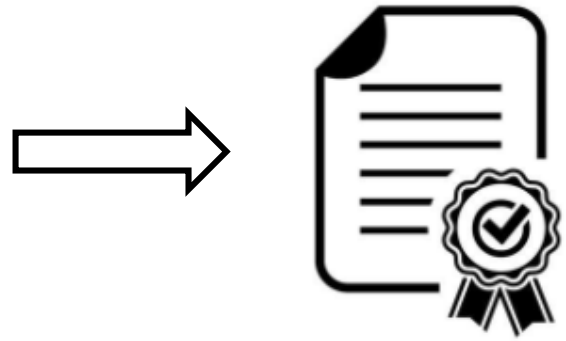
- "The demonstration of compliance with the general safety and performance requirements must also include a clinical evaluation in accordance with Article 61 MDR“, Art. 21 para. 3 MedDO

Conformity assessment

- "Any person placing a medical device on the market must be able to prove that it has been submitted to the prescribed procedures for assessing conformity." Art. 46 TPA

- Conformity assessment procedure according to Art. 23 MedDO and Annexes IX – XI MDR
  - if applicable with the involvement of a designated body

→ Outcome: **Declaration of conformity** and, if applicable, certificate issued by a designated body



Certificates

- Issued by a designated body:
  - bodies designated by Swissmedic in CH
  - notified bodies domiciled in EU/EEA states

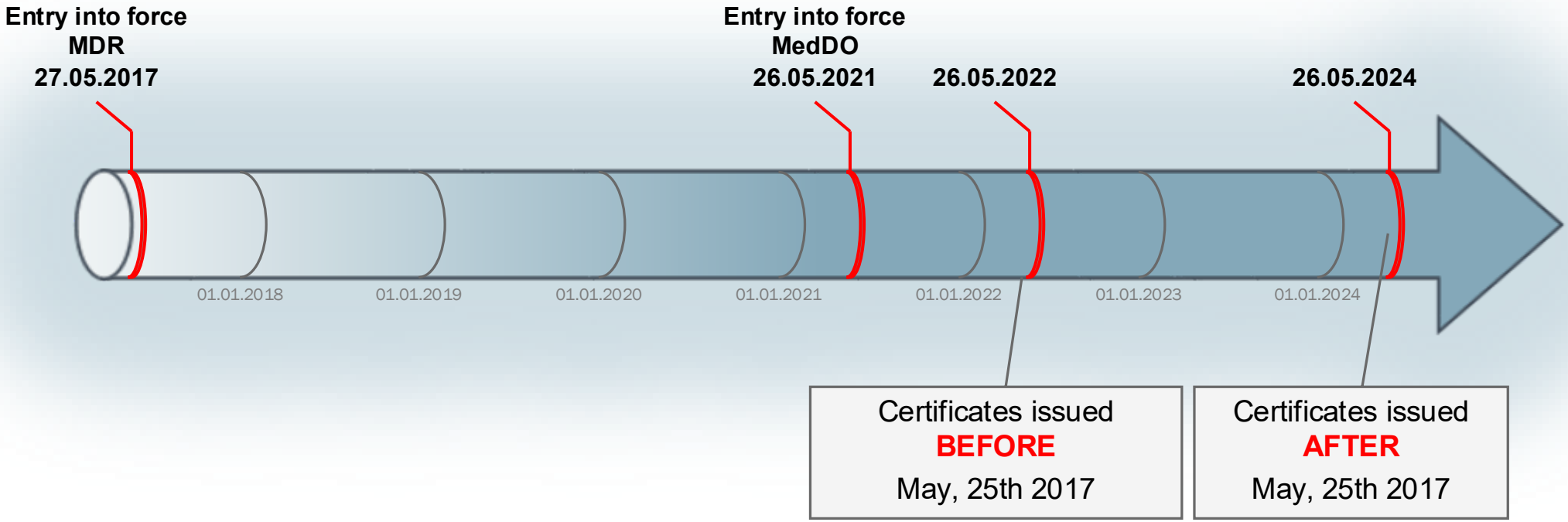
- MDR certificates
  - At least the information stated in Annex XII MDR
  - No CH-specific ruling!
    > No need to state additionally the CHRN, CH-authorised representative or MedDO

- Validity according to certificate, subject to a maximum of 5 years

- Designated body monitors manufacturers during the validity of the certificate

Validity of certificates issued under the old legislation

- Transitional provisions, Art. 100 MedDO



Certificates – Q&A

For what devices is a certificate required?

- A certificate is required for most, but not all, medical devices. Whether a certificate is required depends on the risk class of the device.

The supplier has sent me certificates that relate to standards (e.g. ISO 13485, ISO 9001, IEC 60601-1). Are these sufficient?

- No. Standards certificates are not accepted as certificates and do not prove that a medical device is compliant.

How can I check whether the existing certificate has been issued by an appropriately authorised designated body?

- The Swiss Association for Quality and Management Systems (SQS, identification number 1250) is the only designated body in Switzerland.
- The *NANDO Information System* lists all European bodies that are currently authorised to issue certificates for medical devices.

Device surveillance

- For each device, manufacturers must plan, establish, document, implement, maintain and update a **post-market surveillance system** in a manner that is proportionate to the risk class and appropriate for the type of device. This system forms an integral part of the manufacturer's quality management system.

- *Basis* *Chapter 7 MedDO*

Post-market surveillance

- Manufacturers operate a post-market surveillance system (Art. 56 MedDO)
  - Part of the quality management system
  - Adapted to the type and risk class of the device
  - Planning and regular updating (Art. 58 MedDO)

- Active and systematic gathering of data on quality, performance and safety throughout the device's entire lifecycle
- Data analysis and, if applicable, implement preventive and corrective actions

Class I devices (Art. 59 MedDO):

- Updating the ***post-market surveillance report*** when necessary
- The ***post-market surveillance report*** is part of the technical documentation on post-market surveillance (Annex III MDR)

Safety report (device classes IIa, IIb and III)

- Periodic Safety Update Report (PSUR), Art. 60-62 MedDO in conjunction with Art. 86 MDR
  - Results and conclusions of the analysis of the gathered data
  - Preventive or corrective actions taken
  - Conclusions of the benefit-risk determination
  - Main findings from post-market clinical follow-up
  - Quantities and other information relating to device use

- Regular updating:
  - Class IIa: when necessary and at least every two years
  - Classes IIb and III: at least annually
  - In addition: Review of the PSUR by designated body for class III or implantable devices (Art. 62 para. 2 MedDO)

- Part of the technical documentation specified in Annexes II and III MDR

Summary of safety and clinical performance (Art. 63 MedDO)

- **Class III devices & implantable devices** (excluding custom-made and investigational devices)
- Content includes:
  - Intended purpose, indications and contraindications
  - Diagnostic or therapeutic alternatives
  - Summary of clinical evaluation
  - Profile and training for users
  - Residual risks, undesirable effects, warnings and precautions

- Publicly available -> transparency!
- Written in a way that is understandable to users and patients
  - Published by manufacturer,
  - Information on availability on the label or instructions for use

Summary of Safety and Clinical Performance (SSCP), Art. 63 MedDO in conjunction with Art. 32 MDR

Take-home message

- Revised Medical Devices Ordinance imposes additional and stricter requirements on manufacturers
  - Particularly as regards clinical evaluation and device surveillance

- Greater transparency for economic operators, users and patients
  - Definition of roles, registration requirement
  - Regularly updated safety reports,
  - Summary of safety and clinical performance publicly available

- Foreign manufacturers require a CH-authorised representative

- Check own role before transferring/supplying a device, particularly in the case of:
  - changes to the device or intended use
  - making devices available on the market under the manufacturer's own name or trademark
  - systems and procedure packs

  → Question: do manufacturer obligations have to be assumed?

Thank you for your valued attention