NUFER·MEDICAL

Nufer Medical – let's find the best solutions

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Certified according to ISO 13485

Information to all manufacturers / suppliers who deliver medical devices to Switzerland.

To the responsible persons in your organization

Mutual Recognition Agreement (MRA)

(Agreement between the Swiss Confederation and the European Union on mutual recognition in relation to conformity assessment).

Updated information on our letter no. 18.048._ dated March 04, 2021

On behalf of the Federal Council, the Swiss Federal Office of Public Health (FOPH) has prepared an amendment to the Medical Devices Ordinance («Contingency MedDO») as a precautionary measure, **which will be put into force by the Federal Council on 26 May 2021** if the Mutual Recognition Agreement (MRA) between Switzerland and the European Union (EU) has not been updated by that date. Due to the time pressure under which the medical technology industry is operating, we would like to inform you in this letter about some important contents of the Contingency MedDO. Please note that an update of the MRA before 26 May 2021 is not excluded. In that case, the Contingency MedDO would not enter into force.

Important contents of the Contingency MedDO (not yet passed)

The Contingency MedDO provides **transitional periods** for the appointment of a Swiss representative, including corresponding labelling, **staggered according to risk classes**:

- **Until 31 December 2021** for class III devices, class IIb implantable devices, and all active implantable devices
- **Until 31 March 2022** for non-implantable class IIb devices and class IIa devices.
- **Until 31 July 2022** for Class I devices, systems and procedure packs.

Registration and notification obligations do not run via EUDAMED, but via the Swiss Agency for Therapeutic Products **Swissmedic**. Economic operators who have already placed products on the market before 26 May 2021 in accordance with the MDR and IVDR must complete their registration by 26 November 2021.

Access to the **technical documentation** may be provided either by keeping a copy available at the authorised representative or by contractually guaranteeing that it will be handed over to Swissmedic upon request within 7 days.

The **validated Summary of Safety and Clinical Performance** (SSCP, for class III devices, class IIb implantable devices, and all active implantable devices) is not uploaded by the Notified Body in EUDAMED, but published by the manufacturer, for example on its website.

These **transition periods** are intended to ensure that, as far as possible, all medical devices imported into Switzerland today can still be imported/delivered to Switzerland **after May 26, 2021 without a Swiss authorized representative.** If you have any questions in this matter, please do not hesitate to contact us.

NUFER MEDICAL AG

Daniel Urfer
Managing Director