



## YOUR SWISS MEDICAL DEVICES EXPERT

### SWISS AUTHORISED REPRESENTATIVE **WHAT WE PROVIDE** **MEDDO 812.213**

On 26 May 2021, the European Regulation 2017/745 known as MDR enters into force and replaced the European Directive 93/42 so called MDD.

Until that date, medical devices CE marked under MDD, were recognized in Switzerland because of the Mutual Recognition Agreement signed between Switzerland and Europe.

The failure to sign this MRA updated with the requirements of the MDR between Europe & Switzerland obliges Non-Swiss legal manufacturers of medical devices to follow the requirements of the MedDO ( Swiss Medical Device Ordinance) and so to have a Swiss Authorised Representative to sell their CE-marked devices in Switzerland.

A Swiss Authorised Representative is required both for medical devices CE marked under the new EU MDR and for so-called "legacy devices" (CE marked under the MDD).

To fulfil MedDo requirements by:

- Being your legal representative to access to MD Swiss market,
- Ensuring the interface with SwissMedic for:
  - \* Registration
  - \* Vigilance
  - \* Communication of Trending Report
  - \* Communication of the Technical Documentation and samples
  - \* Verifying the compliance of the Technical Documentation against MedDO,
- To manage and follow-up your Swiss partners (Visit, Audit and QBR).
- To implement a Quarterly Business Review.

### WHY GMB

Our expertise and experience in the Medical Devices industry.

Services tailored to your needs.

Our main preoccupation is the respect of the Swiss medical devices regulation and to ensure the pursue of your business in Switzerland.

Our ability to understand the regulation and guide you through the regulatory pathway.

A strong experience and collaboration with international key medical companies.

Contact us now to choose GMB as your Swiss Authorised Representative and start the process.

### TIMELINE

- Swiss Authorised Representative by:
  - \* 31 December 2021 for Class III, Implantable IIb and Active Implantable MD,
  - \* 31 March 2022 for Class IIa and Class IIb,
  - \* 31 July 2022 for Class I.

#### Contact:



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