Swiss Authorized Representative

Your passport to medical device market access in Switzerland.

Switzerland no longer has a mutual agreement with the EU. As a result, all medical device manufacturers wanting to keep or place their products on the Swiss market are required to appoint a Swiss legal representative.

We offer a highly compliant and professional service that helps manufacturers bring products successfully to the Swiss market.

Our clear and simple approach:

Step 1: Verification
After signing an NDA, we will ask you for access to high-level documentation to verify whether it is feasible for us to be your representative. For this we request the following documents:

- CE certificate and ISO 13485 certificate
- Your product liability insurance policy
- A risk management file, clinical evaluation file (including PMS/PMCF plan/reports), IFU, and labeling of a representative product or product group
- Your SOP on the authorized representative process

Upon validation of verification, we will provide you with our standard agreement.

Step 2: Before getting started
We will need proof of an updated product liability insurance policy covering MD-CLINICALS as an authorized representative. This is an important step as we will be taking local responsibility for your product on the Swiss market.

Step 3: Signing and getting started
After receiving the final insurance policy, MD-CLINICALS will countersign the agreement and we are then ready to get started. You will receive our local registration number for adapting your labeling. We will proceed with a full review of your file before registering your product with Swissmedic. For this, we will provide you with secured access to a local server where you can provide us with up-to-date documents from your product technical file.

After a review of the appropriate documents in your technical file, we will proceed with the registration of your product(s) in the Swiss medical device database.

For further inquiry, please contact SwissAR@md-clinicals.com

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