

SWISS AUTHORIZED REPRESENTATIVE (CH REP)



Choose Thema as your CH REP

Thema is part of CompLife Group and provides the CH REP service through CompLife Swiss, a branch of the Group. Thema will be your point of reference in this market, ensuring compliance with all Swiss regulatory requirements and independence from your Importer or Distributor.

You can activate the service in 3 steps:

Step 1 >



Documentation Screening

Review of your full Technical Documentation (TD) & Quality System (QS) documentation and updating recommendations to comply with the Swiss regulations.

- **One-time activity:** nevertheless each time you change your TD you must inform us;
- **managed with hourly fees:** you pay only for the hours you use;
- **this step is mandatory:** in order to proceed to step 2 we need to make sure that your documentation is correct and complete.

Step 2 >



Appointment of CH REP

It takes place by signing a **Quality Technical Agreement (QTA)** needed to regulate the relationships between the Manufacturer and the CH REP.

- **The mandate is activated:** the responsibility to comply with the CH regulations is shared with the Manufacturer;
- **fixed annual fee.**

Step 3 >



Post-mandate activities

- **Registration** in Swissmedic database;
- **handling communications** with Swissmedic;
- **checking the Manufacturers DHR** (i.e. batch records);
- carrying out **post-market surveillance activities.**

Step 3 activities are managed through hourly fees: **you only pay for the hours you use.**