swissmedic

The tasks of Swissmedic – Lifecycle of a medical device

The different stakeholders in the process

DB / designated body · Swissmedic · Manufacturer

Phase 1: Pre-market development to market conformity
(before market launch)

Phase 2: Market launch

Phase 3: Post-market surveillance
(after market launch)

Products by risk class

Risk class III
e.g. artificial hip joint, artificial heart, cardiac pacemaker

Risk class IIb
e.g. intraocular lenses, insulin pumps

Risk class IIa
e.g. surgical gloves, ultrasound equipment

Products with no medical intended use*
e.g. contact lenses without vision correction, equipment for removing tattoos or hair

Risk class Is / Im / Ir
e.g. sterile plasters, patient scales, reusable surgical instruments

Risk class I
e.g. wheelchair

Risk class A
e.g. sample containers, laboratory analysers

Risk class B
e.g. pregnancy tests

Risk class C
e.g. devices for self-use for blood glucose testing, breast cancer test

Risk class D
e.g. Sars-CoV-2 test, Ebola test

Intended use and classification / Borderline issues

Quality management system: responsibilities, procedures, processes and management resources to ensure compliance with ordinance(s

The DB audits the quality management system

- Approval and monitoring of clinical trials with non-CE-labelled or off-label-use medical devices with or without a medicinal product component
- Approval and monitoring of combined trials with medicinal products and non-CE-labelled or off-label-use medical devices (e.g. companion diagnostics)
- Inspections of clinical trials

Evaluate clinical data/performance evaluation, complete clinical evaluation report/performance report and instructions for use, assess compliance with fundamental requirements

Involvement of a DB

Special additional procedures for:
- certain products in Class III and IIb
- tissues or cells of human or animal origin or their derivatives
- substances or combinations of substances that are absorbed by the human body or distributed locally in the body

The manufacturer is responsible for verifying safety and performance

Involvement of a DB

Special additional procedures for:
- certain class D products

The manufacturer issues the Declaration of Conformity

CE nnnn

CE

CE nnnn

Issuing of registration number (CHRN**)

Registration of stakeholders

If necessary, the application for exemptions is approved

Process notifications concerning:
- Custom-made devices
- MEP and IVD (in-house products) made and used in health establishments
- Relabelled/repackaged MEP and IVD
- DEVIT products (until a special ordinance is enacted)
- IVD, class I products, systems and procedure packs, MEP-DEVIT (until product registration is possible according to oMedDO***)

Issue export certificates (FSC)

PMS plan, PMSR (for Class A, B and I), PSUR (for Class IIa, IIb, III, C and D), serious events, FSCA, PSR, trend report by manufacturer

- Collect and evaluate vigilance reports
- Publication of field safety notices (FSN) (e.g. recalls)

Administrative proceedings
The Agency receives suspicion reports, implements the necessary corrective actions in a risk-based manner and monitors implementation.

Designation/renewal of designation of the DB

Surveillance of the DB

Inspections of hospitals (reporting system, reprocessing and maintenance) and companies (*for cause* and provision of support to foreign authorities)

*Consider Commission Implementing Regulation (EU) 2022/2347 of 1 December 2022 as regards reclassification of groups of certain active products. without an intended medical purpose **CHRN = Swiss Single Registration Number ***Medical Devices Ordinance of 17 October 2001 (version of 1 August 2020)