swissmedic

New regulations on in vitro diagnostic medical devices

Thursday, 3 November 2022

Collection of links from the online event

You can find all the presentations [here]

You can find the general legal framework under point 2 and further information under the relevant headings. Note: This summary is for information purposes only and is not a complete summary of the relevant legal requirements.

1. Swissmedic as safety and industry monitoring authority for therapeutic products

Field safety corrective actions (FSCA): https://fsca.swissmedic.ch/mep/

2. New regulation

Laws, ordinances and international agreements

TPA: Therapeutic Products Act SR 812.21

HRA: Human Research Act SR 810.30

MedDO: Medical Devices Ordinance SR812.213

ClinO-MD: Ordinance on Clinical Trials with Medical Devices SR 810.306

IvDO: Ordinance on In Vitro Diagnostic Medical Devices SR 812.219

MDR: Regulation (EU) on Medical Devices 2017/745

IVDR: Regulation (EU) on In vitro Diagnostic Medical Devices 2017/746

MRA-2017 (not updated): SR 0.946.526.81

Additional information

Frequently Asked Questions: FAQ

Swissmedic Newsletter: NEW > Registration form for Swissmedic News Services (mailxpert.ch)

Roundtable on Medical Technology: Round Table on Medical Technology (RTMT) (swissmedic.ch)

Explanatory report: Ordinance on In Vitro Diagnostic Medical Devices and amendment of the Ordinance on Clinical Trials with Medical Devices: https://www.bag.admin.ch/dam/bag/de/dokumente/biomed/heilmittel/meprrevision/BRB-mai2022/10_erlaeuterungen_ivdv_klinv-mep.pdf.download.pdf/10_erlaeuterungen_ivdv_klinv-mep_de.pdf

Notice to stakeholders: https://health.ec.europa.eu/latest-updates/notice-stakeholders-status-eu-switzerland-mutual-recognition-agreement-mra-vitro-diagnostic-medical-2022-05-24_en

EUDAMED3: EUDAMED database - EUDAMED (europa.eu)

3. Performance studies with IVDs

KOFAM IVD categoriser

www.swissmedic.ch/performance-studies-en

Swissmedic information sheet: www.swissmedic.ch/md-clinicaltrials-en

swissethics guidance document on ‘Substantial modifications’: www.swissethics.ch

4. Vigilance and market surveillance

Swissmedic Materiovigilance: www.swissmedic.ch/md-materiovigilance

Reporting incidents & FSCAs: Reporting incidents & FSCAs (vigilance) (swissmedic.ch)
Economic operators: Economic operators (swissmedic.ch)
Professionals and healthcare institutions / laboratories Users (swissmedic.ch)
Procurement in health institutions: Procurement (swissmedic.ch)

5. Manufacturer

Sources, references and information

Manufacturer's obligations

Definition: Art. 4 para. 1 let. e IvDO
Obligations: Art. 39-43 IvDO, Art. 10 IVDR
Assumption of manufacturer's obligations by third parties: Art. 16 paras. 1 and 2 IVDR
Notification to Swissmedic: IVD notification (swissmedic.ch)

General Safety and Performance Requirements (GSPR)

Art. 6 IvDO, Annex I IVDR
Designated standards: Art. 45 para. 4 TPA, information from Switec
Common specifications: Art. 45 para. 4 TPA, see relevant EU IVDR implementing regulations, currently Implementing Regulation (EU) 2022/1107

Performance evaluation

Art. 39 para. 3 IvDO, Art. 56 and Annex XIII IVDR
Clinical evidence: MDCG 2022-2
Software: MDCG 2020-1

Classification

Art. 14 IvDO, Annex VIII IVDR
Classification guidelines: MDCG 2020-16
Classification of software: MDCG 2019-11

Conformity assessment

Art. 17 and 19 IvDO, Art. 48 and Annexes IX-XI IVDR
Class D verification by NB: MDCG 2022-3

Legacy devices: Transitional periods and manufacturers' obligations

Art. 81 -82 IvDO
Application of IVDR requirements to legacy devices: MDCG 2022-8
Significant changes: MDCG 2022-6

Post-market surveillance

System: Art. 49 and 50 IvDO, Art. 78 para. 3 IVDR
Post-market surveillance plan: Art. 51 IvDO, Annex III para. 1 IVDR
Post-market surveillance report (A&B): Art. 52 IvDO
Safety report (C&D): Art. 53-55 IvDO
General questions: Frequently Asked Questions on medical devices (swissmedic.ch)

6. Authorised representatives, importers and distributors

Further information on our website and especially in the information sheets

for economic operators:
https://www.swissmedic.ch/swissmedic/en/home/medizinprodukte/marktzugang/pflichten-bevollmaechtigte.html

for healthcare institutions: https://www.swissmedic.ch/swissmedic/en/home/medical-devices/reprocessing---maintenance/beschaffung.html