swissmedic
Schweizerisches Heilmittelinstitut
Institut suisse des produits thérapeutiques
Istituto svizzero per gli agenti terapeutici
Swiss Agency for Therapeutic Products

Implementation in Switzerland of EU Commission Implementing Regulation on instructions for use in electronic form

Swissmedic is adopting the new EU requirements for the electronic provision of instructions for use for medical devices with immediate effect

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With the entry into force of EU Commission Implementing Regulation (EU) 2025/1234, the regulations governing the provision of electronic instructions for use have been extended. Swissmedic adopted these requirements with immediate effect, allowing electronic instructions for use intended for professional users in Switzerland too.

On 25 June 2025, Commission Implementing Regulation (EU) 2025/1234 amending Implementing Regulation (EU) 2021/2226 as regards the medical devices for which the instructions for use may be provided in electronic form was adopted in the EU. It has been in force since 16 July 2025.

Where devices are intended for professional users, the permissible scope for electronic instructions for use has been extended to all medical devices and their accessories as well as to products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745 on medical devices (EU MDR) and legacy devices. The instructions for use of devices intended for use by lay persons must continue to be provided in paper form. When registering devices, manufacturers must provide to Eudamed's Unique Device Identifier (UDI) database the internet address under which the electronic instructions for use are accessible.

Repeal of Regulation (EU) 207/2012

Regulation (EU) 2025/1234 has repealed Regulation (EU) 207/2012 on electronic instructions for use of medical devices, to which reference is made in Annex I, Chapter III point 23.1 EU MDR. The old regulation was in force from 25 May 2024 and, until it was fully repealed by

Commission Implementing Regulation (EU) 2025/1234, applied solely to devices that fulfil the requirements of Article 120 para. 3 EU MDR. These devices are referred to as "legacy devices".

What is the situation in Switzerland?

In Switzerland, electronic instructions for use for medical devices were subject to the version of Regulation (EU) 207/2012 specified in Annex 3 number 1.2 of the Medical Devices Ordinance (MedDO, SR 812.213). According to Art. 95 para. 2 MedDO, this was to remain applicable until repealed by an EU Commission Implementing Regulation. Since the European Commission has repealed Regulation (EU) 207/2012 and Swissmedic takes account of Commission Implementing Regulations in accordance with Art. 95 para. 1 MedDO, Commission Implementing Regulations (EU) 2021/2226 and 2025/1234 apply in Switzerland directly and without additional amendments to MedDO.

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