Medical Devices

Medical devices with certification from the former notified body ECM (Aachen DE, identification number 0481): Information from and assessment by Swissmedic

Medical devices and the quality management systems of medical device manufacturers are assessed and continuously monitored by notified bodies. These independent notified bodies contribute to the safety and performance of medical devices. National authorities and the European Commission designate these notified bodies and check whether they meet the requirements of the therapeutic products act and have the necessary competences.

ECM[1] was a notified body for medical devices. Amongst others, it was authorised to certify high-risk devices such as cardiovascular and orthopaedic implants. ECM's notified body status was not renewed by the responsible German authority and expired on 25 May 2020. As of that date, the surveillance of devices certified by ECM in accordance with the requirements of the therapeutic products act was no longer guaranteed.

Swissmedic noticed that medical devices from foreign manufacturers with ECM certificates were still being placed on the Swiss market and therefore decided to inform all Swiss authorised representatives of foreign manufacturers of the matter and their obligations, and to then check compliance with these obligations for a sample.

Information

On 22 June 2023, Swissmedic informed the approximately **980 registered Swiss authorised representatives** about the expiry of the notified body status of ECM. They were requested to review their mandates with the manufacturers and take measures where necessary.

Targeted check July – October 2023

Swissmedic used internal and European databases to identify manufacturers and devices with ECM certificates and compared these with reports of serious incidents from Swiss hospitals. Based on this analysis and further information, Swissmedic specifically selected a sample of **15 authorised representatives** for assessment.

[1] ECM-Zertifizierungsgesellschaft für Medizinprodukte in Europa GmbH (Aachen, DE); identification number 0481.

Results

- 8 authorised representatives had no manufacturers with ECM certificates under contract, for example because new certificates from another notified body were already available for the devices.

- **7 authorised representatives** had devices covered by **ECM certificates** in their portfolio. Despite prior communication, neither suitable measures had been taken nor had the matter been clarified with Swissmedic in another way. Swissmedic is ordering corrective measures for such authorised representatives to ensure that the devices placed on the market in Switzerland fulfil the requirements of the therapeutic products act.

Responsibility

The Swiss authorised representatives are the key players in the Swiss medical device regulatory system. The targeted assessments showed that some authorised representatives do not observe their responsibilities to a sufficient extent. Swissmedic reminds the Swiss authorised representatives that they:

- have a duty of care,

- are responsible for formal and safety-relevant interests in connection with the placing on the market of medical devices, and

- are liable for defective devices (jointly with the manufacturer).

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Swissmedic, Swiss Agency for Therapeutic Products
Medical Devices Surveillance
Hallerstrasse 7
3012 Bern
www.swissmedic.ch