To:
Swiss authorised representatives (CH-REP)

Bern, 22.06.2023

Request to check mandates relating to ECM certifications

Dear Sir/Madam

Swissmedic is responsible for the market surveillance of medical devices in Switzerland. As part of our market surveillance remit we would like to draw your attention to the following matter relating to **ECM – Zertifizierungsgesellschaft für Medizinprodukte in Europa mbH,** Aachen, **NB ID no. 0481 (hereinafter "ECM")**. Unfortunately, it is not currently possible to send targeted information to the CH-REPs affected as product registration has not yet been implemented. We are therefore sending this information to all CH-REPs registered with Swissmedic and are publishing it on the Swissmedic website.

Please take **due note** of the following information about ECM and:

1. In this respect, **check** all products for which you, as CH-REP, are responsible and – where required – institute the necessary **measures** within the scope of your obligations as CH-REP.
2. It is **not necessary** to send a general **acknowledgement** or confirmation of receipt to Swissmedic.
3. Please note: If a CH-REP gives notice to terminate their mandate because the manufacturer has violated its obligations arising from the EU-MDR[1], they must report the termination of their mandate to Swissmedic.[2]

Until 25 May 2020, ECM was a notified body for the assessment of medical devices' conformity with the former European MDD[3]. Notified body status was not renewed and expired on 25 May 2020 (source: NANDO). On 26 May 2021, i.e. about a year after ECM's notified body status had expired, the EU-MDR entered into force. According to the

[1] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.
[2] Art. 51 para. 3 MedDO in conjunction with Art. 11 para. 6 EU-MDR. A notification in accordance with Art. 11 para. 6 EU-MDR may be sent to chrn@swissmedic.ch.
[3] Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

transitional EU-MDR provisions[4], the notified body that issued the certifications under the old legislation in accordance with the MDD remains responsible for the proper surveillance of current requirements regarding the products it certified. However, according to the considerations stated in two German court rulings (see sources), **the transitional provisions regarding surveillance are not applicable to ECM**.
A publication in the German *Medizinprodukte Journal*, issue no. 4 / volume 29, November 2022, pages 348-356, summarises these considerations as follows: *"The OVG* [supreme administrative court of Schleswig-Holstein] *confirms the ruling of the VG* [administrative court of Schleswig-Holstein] […] *and states that Art. 120 para. 3 EU-MDR only relates to cases in which designation of the notified body as per Art. 120 para. 1 EU-MDR has become void,* ***for which reason the transitional provisions shall not apply to the notified body ECM because ECM's status as a notified body has expired due to deficiencies in the performance of its duties****."*

Thank you for noting this information.

Kind regards
Swissmedic, Swiss Agency for Therapeutic Products

Sources and references:

1	Expiry of ECM's notified body status NANDO > Body > Withdrawn/Expired/Suspended Notifications/NBs Direct LINK
2	ECM website with information regarding activities as notified body https://www.medi-online.com/
3	Ruling of Administrative Court of Schleswig-Holstein dated 23.06.2021 https://www.gesetze-rechtsprechung.sh.juris.de/perma?d=MWRE210002613
4	Ruling of Supreme Administrative Court of Schleswig-Holstein dated 23.09.2021 https://www.gesetze-rechtsprechung.sh.juris.de/perma?d=MWRE210003848
5	Information from Swissmedic on the obligations of Swiss authorised representatives Swiss authorised representatives (CH-REP) (swissmedic.ch)

[4] Previously Art. 120 para. 3 MDR; since the Amendment by Regulation (EU) 2023/607 of the European Parliament and the Council of 15 March 2023, the provision is in Art. 120 para. 3e EU-MDR.