kviknaMedical

Extension of CE Certificate – Stratus EEG

On 15 March 2023 the European parliament and the council of the European Union issued an amendment to Regulation (EU) 2017/745 (MDR), Regulation (EU) 2023/607. The regulation was published in the Official Journal of the European Union on 20 March 2023, entering into force on the day of its publication.

The regulation extends the validity of certificates issued in accordance with Directives 90/385/EEC and 93/42/EEC and extends the transitional period during which devices that are in conformity with those Directives can lawfully be placed on the market. The regulation is intended to prevent a shortage of medical devices in the area as the industry struggles to meet the original timelines set in the MDR.

Regulation (EU) 2023/607, Article 1 > (a) states the following:

> *Certificates issued by notified bodies in accordance with Directives 90/385/EEC and 93/42/EEC from 25 May 2017 that were still valid on 26 May 2021 and that have not been withdrawn afterwards shall remain valid after the end of the period indicated on the certificate until the date set out in paragraph 3a of this Article applicable for the relevant risk class of the devices. Certificates issued by notified bodies in accordance with those Directives from 25 May 2017 that were still valid on 26 May 2021 and that have expired before 20 March 2023 shall be considered to be valid until the dates set out in paragraph 3a of this Article only if one of the following conditions is fulfilled:*
>
> *(a) before the date of expiry of the certificate, the manufacturer and a notified body have signed a written agreement in accordance with Section 4.3, second subparagraph, of Annex VII to this Regulation for the conformity assessment in respect of the device covered by the expired certificate or in respect of a device intended to substitute that device.*
>
> *(b) a competent authority of a Member State has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) of this Regulation or has required the manufacturer, in accordance with Article 97(1) of this Regulation, to carry out the applicable conformity assessment procedure.*

Article 1 > (b) > 3 of the amendment also states:

> *Devices which have a certificate that was issued in accordance with Directive 90/385/EEC or Directive 93/42/EEC and that is valid by virtue of paragraph 2 of this Article may be placed on the market or put into service until the following dates:*
>
> *(a) 31 December 2027, for all class III devices, and for class IIb implantable devices except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors.*

(b) 31 December 2028, for class IIb devices other than those covered by point (a) of this paragraph, for class IIa devices, and for class I devices placed on the market in sterile condition or having a measuring function.

Furthermore, Article 1 > (b) > 3c states:

Devices referred to in paragraphs 3a and 3b of this Article may be placed on the market or put into service until the dates referred to in those paragraphs only if the following conditions are met:

(a) those devices continue to comply with Directive 90/385/EEC or Directive 93/42/EEC, as applicable.

(b) there are no significant changes in the design and intended purpose.

(c) the devices do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health.

(d) no later than 26 May 2024, the manufacturer has put in place a quality management system in accordance with Article 10(9).

(e) no later than 26 May 2024, the manufacturer or the authorised representative has lodged a formal application with a notified body in accordance with Section 4.3, first subparagraph, of Annex VII for conformity assessment in respect of a device referred to in paragraph 3a or 3b of this Article or in respect of a device intended to substitute that device, and, no later than 26 September 2024, the notified body and the manufacturer have signed a written agreement in accordance with Section 4.3, second subparagraph, of Annex VII.

Kvikna Medical ehf has marketed the Stratus EEG device since 2015. The device is a class IIa medical device according to the MDD (Directive 93/42/EEC). Kvikna Medical has actively been working with BSI since November 2020 on the MDR transition. This is ongoing.

BSI (Notified Body Number 2797) issued on 26 February 2019 a CE certificate, CE 664137, to Kvikna Medical ehf relating to the Stratus EEG medical device (software intended for use in clinical EEG) that was valid until 26 April 2022. Additionally, Kvikna Medical signed an agreement with BSI in accordance with Section 4.3, first and second subparagraph, of Annex VII in November 2020.

Since Kvikna Medical ehf has a CE certificate that was issued after 25 May 2017 and was valid on 26 May 2021, as well as a written contract with BSI, a notified body, for the conformity assessment before the expiry of the CE certificate, it is clear that the company has fulfilled the conditions set forth in Article 1(a) of the amendment.

In relation to Article 1(b), Kvikna Medical ehf has already implemented a quality management system in accordance with Article 10(9) of the MDR as requested by (c), this was audited by BSI in October 2021. This system ensures that the conditions set forth in 3c. (a) and 3c. (c) are met. As for 3c. (b), the intended use of Stratus EEG is unchanged since the issue of the certificate and there are no significant changes in the design. As stated above, Kvikna Medical ehf has already a written agreement with BSI in accordance with Section 4.3, (first and) second subparagraph, of Annex VII as requested by 3c. (e).

Therefore, based on the above arguments and the amendment to Regulation (EU) 2017/745, it is concluded that the CE certificate for the Stratus EEG is extended until the dates set out in Article 1, paragraph (b) for the relevant risk class of the device, this is 31 December 2028 as the risk-class of the device is IIa.

Reykjavík,
20 March 2023

Garðar Þorvarðsson,
CEO Kvikna Medical ehf