

Evondos Oy
Teknologiantie 7b
90590 Oulu
Finland

Notification of Change 2024-12-05

Subject Letter of confirmation related to certification of quality system and product range, based on Council Directive 93/42/EEC concerning medical devices, Annex II (excluding Section 4) and on transitional provisions of Article 120 of Medical Device Regulation (EU) 2017/745 and on MDCG guideline 2020-3, to complement information on the existing certificate.

Manufacturer Evondos Oy, Teknologiantie 7b, 90590 Oulu, Finland

Decision On the related certificate and its Attachment 1, the following changes are identified:

- The company name is changed from *NE Device SW Oy* to *Evondos Oy*
- Product labelling material is updated accordingly

There are no changes in the QMS or address.

Justification SGS Fimko Ltd confirms that the change covered by this Letter of Confirmation do not represent a significant change in design or intended purpose meant in Article 120 of MDR (EU) 2017/745 and that the related MDD certificate remains valid.

SGS Fimko Ltd has assessed manufacturer's quality management system and products. Quality management system and products meet the requirements of Annex II (excluding Section 4) of Medical Device Directive 93/42/EEC and the applicable transitional provisions of Article 120 of Medical Device Regulation (EU) 2017/745.

The decision is based on the analysis of manufacturer's Notification of Change, dated 2024-12-05.


The manufacturer has signed the undertaking to follow the obligations of Annex II of the Directive 93/42/EEC and of the MDR (EU) 2017/745 Article 120.

Certificate related to decision FI/21/871845 Issue 1
Attachment 1

Attachment to certificate LoC#1 dated 2023-07-06
LoC#2 dated 2024-09-19

Valid until This decision is valid until 31 December 2028 providing the requirements of the certification are fulfilled. The certificate and its attachment listed above are not valid without this Letter. In case of requests from authorities, the manufacturer should number the letters of confirmation received from the notified body and submit them together with the certificate.

Date Helsinki, 13 December 2024



Seppo Vahasalo, Notified Body Manager
SGS Fimko Ltd, Notified Body 0598