




Regulation (EU) 2017/745 (MDR)
NOTIFIED BODY COMMUNICATION LETTER
**Resolution on the manufacturer's notification of change to the quality system
or the product-range**

Manufacturer	Franke Medical Oy => KWC Nordics Oy
Date of notification	2 March 2022
Received by Eurofins ES, date	3 March 2022
Annex of MDD	Annex II
Product and product class	Washers and disinfectors for treating of medical materials; class IIa
Description of the changes	<p>Franke Medical Oy has merged into Franke Finland Oy. The name of the new company is KWC Nordics Oy starting from 1.3.2022. Also the business ID is 0958736-2 starting from 1.3.2022.</p> <p>The change affects both the valid certificate and its two attachments (certificate C-01-1035-745-20): The only change in the certificate is the name of the company.</p>
Material dispatched by manufacturer	See Change assessment report: NB-1035-MR10

Change assessed by	Tiia Tuokko (Aliina Nieminen)
Significance of the change	The change is considered as an administrative change according to the principles of the MDR Article 120 and MDCG 2020-3 guidance document.
The resolution	<input checked="" type="checkbox"/> The change is approved and is considered non-significant in the intended purpose or design of the device. <input type="checkbox"/> The approval of the change affects <u>the attachment</u> related to the valid certificate. The manufacturer shall attach this “ <i>NOTIFIED BODY COMMUNICATION LETTER</i> ” as part of its valid EC-Certificate (MDD 93/42/EEC). <input checked="" type="checkbox"/> The approval of the change affects <u>both the valid certificate and attachment</u> related to it. The manufacturer shall attach this “ <i>NOTIFIED BODY COMMUNICATION LETTER</i> ” as part of its valid EC-Certificate (MDD 93/42/EEC). <input type="checkbox"/> The approval of the change will require a separate audit of the manufacturer, its subcontractor or supplier. <input type="checkbox"/> The change is rejected; it is considered significant in the intended purpose of the device.

	<input type="checkbox"/> The change is rejected; it is considered significant in the design of the device.
Date and signature	4 May 2022 <div style="display: flex; justify-content: space-between;"> <div style="text-align: center;">  Digitally signed by Aliisa Siljander Date: 2022.05.05 08:29:30 +03'00' </div> <div style="text-align: center;">  Tiia Tuokko 2022.05.04 16:13:59 +03'00' </div> <div style="text-align: center;">  Digitally signed by Aliina Nieminen Date: 2022.05.04 16:30:17 +03'00' </div> </div>
	Decision maker Lead auditor
Resolution notified to the manufacturer, date	6 May 2022

Eurofins Electric & Electronics Finland Oy has operated as a notified body (NB-0537) for Directive 93/42/EEC Medical devices (MDD). As from 26 May 2021, the notified body is no longer able to issue new certificates under MDD but only allowed to carry out surveillance activities for certificates validity issued under that Directive in the transitional period, as established in Article 120 of Regulation (EU) 2017/745 (MDR).

According to Article 120 of MDR, certificates issued by notified bodies in accordance with MDD from 25 May 2017 shall remain valid until the end of the period indicated on the certificate, which shall not exceed five years from its issuance. They shall however become void at the latest on 27 May 2024.

Guidance document MDCG 2020-3 (Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD) highlights that no issuing of new MDD certificates, including amended or supplemented certificates, is allowed under MDR Article 120(3). In particular, if the manufacturer wishes to make a “significant change in design or intended purpose” under MDR Article 120(3), the implementation of such a change would prevent the manufacturer from continuing to place that device on the market under the MDD.

It is also important that the MDD certificates remain valid following changes that are not significant with regard to design or intended purpose, provided that the required surveillance is carried out by the notified body that issued the certificate.

For instance, administrative changes of organisations are considered in principle as nonsignificant. This includes changes of the manufacturer’s name, address or legal form (legal entity remains) or changes of the authorised representative.

Furthermore, all changes not having an impact on the design or the intended purpose of the device can be regarded as not significant in the meaning of MDR Article 120(3). This is the case for example of relocation or addition of new manufacturing sites, including when it affects subcontractors or suppliers, or of certain changes of the quality management system, provided that the conditions for which the conformity assessment certification was granted are maintained.

For more information, please refer to MDCG 2020-3 guidance.