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	Mediq Suomi Oy
Date of notification	27th January 2022
Received by Eurofins ES, date	27th January 2022
Annex of MDD	Annex VI
Product and product class	Sinuscan 301, class IIa
Description of the changes	Mediq Suomi Oy address changed from Riihitontuntie 7 D, FIN-02200 Espoo to Vuoritontunkuja 6, FIN-02200 Espoo. The location does not change. Only the address changes. No changes to production. The approval of the change affects both the valid certificate VTT-C-12323-01-1027-636-18 and attachment related to it.
Material dispatched by manufacturer	Documents listed in Change Assessment Report NB-1027-MR15

Change assessor	Rami Haulisto
Significance of the change	The manufacturer has provided sufficient justification for the resolution of the notified change being considered as non-significant in the intended use or design of the product: 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	☒ The change is approved and is considered non-significant in the intended purpose or design of the device. ☐ The approval of the change affects the attachment related to the valid certificate. The manufacturer shall attach this "*NOTIFIED BODY COMMUNICATION LETTER*" as part of its valid EC-Certificate (MDD 93/42/EEC). ☒ The approval of the change affects both the valid certificate and attachment related to it. The manufacturer shall attach this "*NOTIFIED BODY COMMUNICATION LETTER*" as part of its valid EC-Certificate (MDD 93/42/EEC). ☐ The approval of the change will require a separate audit of the manufacturer, its subcontractor or supplier.

	☐ The change is rejected; it is considered significant in the intended purpose of the device. ☐ The change is rejected; it is considered significant in the design of the device.
Date and signature	11th February 2022 Digitally signed by Satu Rajala Date: 2022.02.11 13:03:44 +02'00' Satu Rajala Decision maker Digitally signed by Rami Haulisto Date: 2022.02.11 11:03:05 +02'00' Rami Haulisto Lead auditor
Resolution notified to the manufacturer, date	11th February 2022

Eurofins Expert Services 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.