

DEKRA Certification GmbH – Handwerkstraße 15 – D -70565 Stuttgart

SFM Hospital Products GmbH  
Ms Marion Metag-Karg  
Segelfliegerdamm 67-89  
12487 Berlin  
Germany

**DEKRA Certification GmbH**

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Date 2024-03-07

**Subject: Notified Body Confirmation Letter**

**Our reference: 50759-CoL-00, Rev. 0**

**Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices**

Dear Ms. Metag-Karg

This letter confirms that, DEKRA Certification GmbH, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0124 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

SFM Hospital Products GmbH  
Segelfliegerdamm 67-89  
12487 Berlin  
Deutschland

SRN Number (if available): DE-MF-000005505

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables 1 and 2 below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive MDD. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive MDD.

In the case of devices covered by certificates issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the

date of MDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments).

On behalf of the Notified Body,

Stephanie Donner  
2024-03-07

Enclosures:

Confirmation Letter Annex

**Table 1: Devices covered by this letter and for which the notified body DEKRA Certification GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:**

| Product or product group identification acc. to MDD - certificate | MDD Device classification | MDD Certificate and Certificate Annex No. with revision  |
|---|---------------------------|--|
| Infusion Sets, sterile  | Class IIa                 | EC CERTIFICATE for the Quality Assurance System according the Directive 93/42/EEC, Annex V - Certificate No.: 50759-17-04; with Annex Rev. 0, dated 2019-03-13 |
| Transfusion Sets, sterile   | Class IIa                 | EC CERTIFICATE for the Quality Assurance System according the Directive 93/42/EEC, Annex V - Certificate No.: 50759-17-04; with Annex Rev. 0, dated 2019-03-13 |
| Surgical Gloves, sterile  | Class IIa                 | EC CERTIFICATE for the Quality Assurance System according the Directive 93/42/EEC, Annex V - Certificate No.: 50759-17-04; with Annex Rev. 0, dated 2019-03-13 |
| Syringes for single use with/without Needle, sterile              | Class IIa                 | EC CERTIFICATE for the Quality Assurance System according the Directive 93/42/EEC, Annex V - Certificate No.: 50759-17-04; with Annex Rev. 0, dated 2019-03-13 |
| Insulin Syringes for single use, sterile                          | Class IIa                 | EC CERTIFICATE for the Quality Assurance System according the Directive 93/42/EEC, Annex V - Certificate No.: 50759-17-04; with Annex Rev. 0, dated 2019-03-13 |
| I.V. Cannula, sterile   | Class IIa                 | EC CERTIFICATE for the Quality Assurance System according the Directive 93/42/EEC, Annex V - Certificate No.: 50759-17-04; with Annex Rev. 0, dated 2019-03-13 |
| Scalp Vein Set/Butterfly Cannula, sterile                         | Class IIa                 | EC CERTIFICATE for the Quality Assurance System according the Directive 93/42/EEC, Annex V - Certificate No.: 50759-17-04; with Annex Rev. 0, dated 2019-03-13 |
| Hypodermic Needles for single use, sterile                        | Class IIa                 | EC CERTIFICATE for the Quality Assurance System according the Directive 93/42/EEC, Annex V - Certificate No.: 50759-17-04; with Annex Rev. 0, dated 2019-03-13 |