EG ZERTIFIKAT

zum Qualitätssicherungssystem

gemäß Richtlinie 93/42/EWG, Anhang V

DEKRA Certification GmbH bescheinigt hiermit als Benannte Stelle der Europäischen Union, dass das Unternehmen

SFM Hospital Products GmbH

Segelfliegerdamm 67-89, 12487 Berlin, Deutschland

Zertifizierter Standort:

Segelfliegerdamm 67-89, 12487 Berlin, Deutschland

ein Qualitätssicherungssystem für die in der Anlage genannten Medizinprodukte gemäß Anhang V der Richtlinie 93/42/EWG anwendet. Diese Genehmigung beruht auf dem Ergebnis des Re-Zertifizierungsaudits Bericht Nr. 50759-Z5-00, dem Entscheid von 2019-03-13 und ist nur in Verbindung mit der erfolgreichen Durchführung der jährlichen Überwachungsaudits gültig.

Dieses Zertifikat ist gültig von 2019-03-13 bis 2024-03-12

Registrier-Nr.: 50759-17-04

DEKRA Certification GmbH • DEKRA Certification • D-70565 Stuttgart, Handwerkstraße 15

Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2019-03-13
Benannte Stelle ID-Nummer: 0124

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-295.10.02

Anlage zum Zertifikat Nr. 50759-17-04

gültig von 2019-03-13 bis 2024-03-12

Revisionsstand der Anlage: 0 vom 2019-03-13

In die Genehmigung eingeschlossene Medizinprodukte / Produktkategorien:

Klasse II a:

- Infusionsbesteck, steril
- Transfusionsbesteck, steril
- OP-Handschuhe, steril
- Einmalspritzen mit/ohne Kanülen, steril
- Einmal-Insulinspritzen, steril
- Venenverweilkanüle, steril
- Perfusionsbesteck/Schmetterlingskanüle, steril
- Einmal-Injektionskanülen, steril

Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2019-03-13
Benannte Stelle ID-Nummer: 0124

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
Handwerkstraße 15
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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.

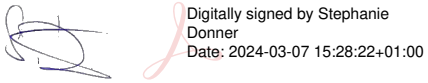
In the case of devices covered by certificates issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the

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