Business Stream Products
Certification Department

TÜVRheinland®
LGA
Precisely Right.

TÜV Rheinland LGA Products GmbH • 51105 Köln

Med SSE System GmbH
Herderstr. 5-9
90427 Nürnberg
Germany

Contact

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Date May 28, 2024

Notified Body Confirmation Letter
Reference: MEDSS_PLA0_HZ_2024-05-23

To whom it may concern,

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 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

This letter confirms that **TÜV Rheinland LGA Products GmbH**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **0197** 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:

Med SSE System GmbH
Herderstr. 5-9
90427 Nürnberg
Germany
SRN Number (if available): DE-MF-000008104

The devices covered by the formal application and the written agreement mentioned above are identified in the tables 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 under the applicable Directive. 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.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after May 26, 2021 but before March 20, 2023 without having been withdrawn, this letter also confirms that the manufacturer either signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided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 March 20, 2023 for the relevant devices.

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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:

- May 26, 2026 for Class III custom-made implantable devices
- December 31, 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)
- December 31, 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- December 31, 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

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Datum: 2024.05.28 19:06:46 +02'00'

i.V. Dr. Karsten Kluge
Certification body

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

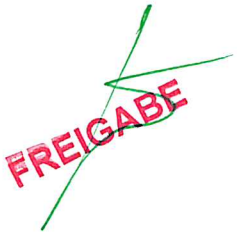
Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Contam	IIa	N/A	DD 60148896 0001 NB 0197
A-Tam-Analtampon	IIa	N/A	DD 60148896 0001 NB 0197
A-Tam-Proktologietampon	IIa	N/A	DD 60148896 0001 NB 0197

Table 2: Devices covered by this letter and for which the NB is <u>NOT</u> responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/05/28	MEDSS_CL607_2024-05-28	Initial issue
YYYY/MM/DD	XXXXXXXXX	Addition of device XYZ to the list
YYYY/MM/DD	XXXXXXXXX	Removal of device XYZ to the list



EG-Zertifikat

Richtlinie 93/42/EWG Anhang V
Qualitätssicherung Produktion
Medizinprodukte

Registrier-Nr.: DD 60148896 0001

Berichts-Nr.: 21246713 012

Hersteller:

Med SSE System GmbH
Alfred von der Lehr
Herderstr. 5-9
90427 Nürnberg
Deutschland

Produkte:

Inkontinenz- und Proktologietampons

(siehe Anlage für einbezogene Produkte)

Ersetzt EG-Zertifikat, Registrier-Nr.: DD 60111016 0001

Gültig bis: 2024-05-26

Hiermit erklärt die Benannte Stelle, dass die Anforderungen nach Richtlinie 93/42/EWG Anhang V für die aufgeführten Produkte erfüllt sind. Der oben genannte Hersteller hat ein Qualitätssicherungssystem eingeführt und wendet es an. Dieses Qualitätssicherungssystem ist Gegenstand einer regelmäßigen Überwachung nach Anhang V Abschnitt 4 der oben genannten Richtlinie. Um Medizinprodukte der Klassen IIb und III, die Gegenstand dieses Zertifikates sind, auf den Markt zu bringen, ist eine EG-Baumusterprüfbescheinigung nach Anhang III erforderlich.

Gültig ab: 2020-04-30

Datum: 2020-04-30

Benannte Stelle

Roland Gruber

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH ist eine Benannte Stelle
nach Richtlinie 93/42/EWG über Medizinprodukte mit der Kennnummer 0197.

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Doc. 1/1, Rev.0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Anlage zum Zertifikat
Registrier-Nr.: DD 60148896 0001
Berichts-Nr.: 21246713 012

Hersteller:
Med SSE System GmbH
Alfred von der Lehr
Herderstr. 5-9
90427 Nürnberg
Deutschland

Einbezogene Produkte:

- PVA - Proktologietampon
- PVA - Vaginaltampon Contam®
- PVA - Analtampon

Benannte Stelle

Datum: 2020-04-30

Roland Gruber

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle