EU Certificate

Production Quality Assurance
REGULATION (EU) 2017/745 on Medical Devices
Annex XI Part A

Registration No.: DZ 1620448-1

Manufacturer: Med SSE System GmbH
Alfred von der Lehr
Andernacher Str. 21a
90411 Nürnberg
Germany

EUDAMED Single Registration No.: DE-MF-000008104

Products:

Products of Class IIa:

U070199 - INCONTINENCE-CONTROL, INTERNAL SYSTEMS - OTHERS

Authorized representative(s): N/A

Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2025-09-16
1	Change of manufacturer address	2026-02-02

The Notified Body hereby declares that the requirements of Annex XI, Part A of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a production quality assurance, which is subject to periodic surveillance, defined by Annex XI, Part A, Section 7 of the aforementioned regulation.
If class III devices or class IIb devices are covered by this certificate, an EU type-examination certificate in accordance with Annex X of the aforementioned regulation is required before placing them on the market.

Report No.: 1202532-20

Effective date: 2025-09-16

Expiry date: 2030-09-15

Issue date: 2026-02-02

Dipl.-Ing. (FH) Martin Wolf
TÜV Rheinland LGA Products GmbH
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This certificate can be validated on https://www.certipedia.com

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.

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