EU-Quality Management System Certificate

Pursuant to Regulation (EU) 2017/745 on Medical Devices,
Annex IX, Chapters I and III

The Notified Body of TÜV NORD CERT GmbH certifies that the manufacturer

Medset Medizintechnik GmbH
Curslacker Neuer Deich 66
21029 Hamburg
Germany

has established, documented and implemented a quality management system in accordance with Article 10, paragraph 9 of Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s). The conformity assessment has been carried out and successfully completed in accordance with Annex IX, Chapters I and III. The result of the assessment, references to investigations carried out, relevant common specifications and test reports are summarised in the report mentioned below. The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The validity of this certificate is based on the maintenance of the quality management system in accordance with the requirements of the Regulation and its regular surveillance by the Notified Body in accordance with Annex IX, Chapter I, Section 3. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.

In addition to the CE marking, the identification number of the Notified Body must be affixed to the devices.

For the placing on the market of class III and Class IIb implantable devices an additional EU technical documentation assessment certificate according to Annex IX, Chapter II is required.

Single Registration Number of the Manufacturer (SRN):	DE-MF-000016442
Authorised Representative:	Medset Medizintechnik GmbH
The validity of this EU Certificate depends on conditions and / or is limited to the following:	--
List of Products, Risk Classification and Details:	see Section 2
Certificate history:	see Section 3

Reg.-No.: 44 911 221064
Certification decision report No.: 3535 3830

Valid from:	2024-07-05
Valid until:	2029-07-04
First issued:	2024-07-05
Issue Date:	2024-07-05
Edition:	1

Essen, 2024-07-05

TÜV NORD CERT GmbH is a Notified Body with identification number 0044

TÜV NORD CERT GmbH
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TÜV®

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-095

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Reg. No. 44 911 221064 Section 2, List of Products

Class IIa

Product name	Category of device (MDx)	Technical documentation assessment report number
PADSY Holter PADSY ECG PADSY Ergo PADSY Spiro PADSY RR	MDA 0315	3535 3831

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Reg. No. 44 911 221064 Section 3, Certificate History

Certificate History

Edition	Date	Action leading to revision	Certification decision report number
1	2024-07-05	Initial issuance	3535 3830

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