EU Certificate

Quality Management System
REGULATION (EU) 2017/745 on Medical Devices
Annex IX Chapters I and III

Registration No.:	HZ 1624046-1
Manufacturer:	GETEMED Medizin- und Informationstechnik AG Oderstr. 77 14513 Teltow Germany
EUDAMED Single Registration No.:	DE-MF-000012384

Products:

Products of class IIa:
Z120302 - INSTRUMENTS TO SUPPORT AND MONITOR VITAL SIGNS

Z120504 HOLTER SYSTEM INSTRUMENTS FOR CARDIOVASCULAR PARAMETERS

Products of class IIb:
Z120302 - INSTRUMENTS TO SUPPORT AND MONITOR VITAL SIGNS
VITAL SIGNS MONITORING INSTRUMENTS

Authorized representative(s): N/A

The Notified Body hereby declares that the requirements of Annex IX, Chapter I of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled.
If class III devices or class IIb implantable devices referred to in the second subparagraph of Article 52(4) are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.9 is required before placing them on the market.

Report No.:	1188229-10
Effective date:	2025-10-10
Expiry date:	2030-10-09
Issue date:	2025-09-23

Dipl.-Ing. Fabian Pilatus
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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.

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-091

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Certificate history		
Revision:	Description:	Issue date:
3	Re-certification. Replaces certificate HZ 1624046-1 rev. 2 issued 2025-04-15.	2025-09-23

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