EU Certificate

Quality Management System
REGULATION (EU) 2017/745 on Medical Devices
Annex IX Chapter I, Section 2 and 3 and Chapter 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: 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, Section 2 and 3 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.:	1161296-200
Effective date:	2025-02-04
Expiry date:	2025-10-09
Issue date:	2025-02-04

Dipl.-Ing. Frank Schwingen
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
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Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2021-09-14
1	Scope extension, products of class IIb: Z120302	2025-02-04

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