

# 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

Authorised  
representative(s): N/A

Certificate history		
Revision:	Description:	Issue date:
1	Initial revision	2021-09-14

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.

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