EU Certificate

Quality Management System
REGULATION (EU) 2017/745 on Medical Devices, Annex IX Chapter I, Section 2 and 3 and Chapter III

TÜVRheinland®

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.

Report No.:	3327066-90
Effective date:	2021-09-14
Expiry date:	2025-10-09
Issue date:	2021-09-14

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

TÜV Rheinland LGA Products GmbH

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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.

Product List and Application MDR
QM part

PRODUCTS:

Note: Please provide an information for all columns (also the blue columns which will not be printed).

No.	Product name or Trade Name (as listed on label)	Type of device using terminology of Basic-UDI-DI, EMDN or GMDN	Basic UDI-DI code	Medical Device Category (for all medical devices)	European Medical Device Nomenclature (EMDN)	Classification of product and classification rule resulting in highest risk class		Summary list of related facilities (use facility codes from Facilities table, i.e IMF(1), IR&D(1))	Code of EU-REP (use facility No from Facilities table)	Technical documentation identifier
					Please use EMDN code 4th level (EMDN code on level 4; Letter + 6-digits; if no level 4 exists, use next upper level)	Device Class	Classification Rule including subclause according to Annex VIII			
1	CardioMem CM 100 XT	Tele ECG Recorder	0425090320238NF	MDA 0204 Other active non-implantable devices for monitoring and/or diagnosis	Z120504	IIa	Rule 10 indent 3	EMF(1) IMF(1) IR&D(1) IR&D(2)	-	1501
2	CardioDay	Software CardioDay Standard	0425090320240N2	MDA 0315 Standalone software	Z120504	IIa	Rule 11	IMF(1) IR&D(1)	-	1450
3	CardioDay	Software CardioDay Easy	0425090320240N2	MDA 0315 Standalone software	Z120504	IIa	Rule 11	IMF(1) IR&D(1)	-	1450
4	HeartX Viewer	Software HeartX Viewer	0425090320241N4	MDA 0315 Standalone software	Z120504	IIa	Rule 11	IMF(1) IR&D(1)	-	2018
5	PhysioMem	Tele ECG Recorder PhysioMem PM 100 4G	0425090320243N8	MDA 0204 Other active non-implantable devices for monitoring and/or diagnosis	Z120504	IIa	Rule 10 indent 3	EMF(1) EMF(2) EMF(3) IMF(1) IR&D(1) IR&D(2)	-	1214

Please add or delete lines as required!