EG-KONFORMITÄTSERKLÄRUNG / EC DECLARATION OF CONFORMITY / DÉCLARATION CE DE CONFORMITÉ / DICHIARAZIONE CE DI CONFORMITÀ

Name und Adresse des Herstellers: / Name and address of the manufacturer: / Nom et adresse du fabricant: / Nome e indirizzo del fabbricante:

GETEMED Medizin- und Informationstechnik AG
Oderstr. 77
14513 Teltow
Deutschland / Germany / Allemagne / Germania

Produkt / Product / Produit / Prodotto:	CardioDay v2.7.1
SRN:	DE-MF-000012384
Basic UDI-DI:	0425090320240N2
Klasse / class / classe:	IIa

Intended Purpose:

The CardioDay Holter Analysis Software is designed for the acquisition, analysis, edit, review, report, and storage of ambulatory and multi-parameter ECG data. Results of the automated analysis are intended to assist the physician in the interpretation of the recorded data. This information is not intended to serve as a substitute for the physician overread of the recorded ECG data. The CardioDay system is intended to be used by trained operators under the direct supervision of a licensed healthcare practitioner in a hospital or clinic environment. Patient population includes both adult and pediatric human patients. CardioDay provides the user arrhythmia study and Holter analysis capabilities.

Gemäß Anhang VIII der Verordnung (EU) 2017/745 erklären wir in alleiniger Verantwortung, dass dieses Medizinprodukt den einschlägigen Bestimmungen der Verordnung (EU) 2017/745 und deren Umsetzungen in nationale Gesetze entspricht. Die Erklärung gilt in Verbindung mit dem Dokument Endprüfprotokoll „FB-0118-04".

In accordance with Annex VIII of Regulation (EU) 2017/745, we declare under our sole responsibility that this medical device conforms to the provisions of Regulation (EU) 2017/745 and its transposition into national law applicable to it. The declaration is valid in connection with the document final inspection report „FB-0118-04".

Conformément à l'annexe VIII du règlement (UE) 2017/745, nous déclarons sous notre seule responsabilité que ce dispositif médical est conforme aux dispositions pertinentes du règlement (UE) 2017/745 et à ses transpositions en droit national. La déclaration est valable en relation avec le document rapport de l'inspection finale „FB-0118-04".

In conformità all'Allegato VIII del Regolamento (UE) 2017/745, dichiariamo sotto la nostra esclusiva responsabilità che questo dispositivo medico è conforme alle disposizioni pertinenti del Regolamento (UE) 2017/745 e ai suoi recepimenti nella legislazione nazionale. La dichiarazione è valida insieme al rapporto di prova del prodotto finale "FB 0118-04".

Konformitätsbewertungsverfahren: /	Verordnung (EU) 2017/745 Anhang IX Kapitel I
Conformity assessment procedure: /	Regulation (EU) 2017/745 Annex IX Chapter I
Procédure d'évaluation de la conformité: /	Règlement (UE) 2017/745 Annexe IX Chapitre I
Procedura di valutazione della conformità:	Regolamento (UE) 2017/745 Allegato IX Capo I

Registrier-Nr.: / Registration No.: / N°d'enregistrement: / Numero di registrazione:
HZ 1624046-1

Benannte Stelle: / Notified Body: / Organisme notifié: / Organismo notificato:

TÜV Rheinland LGA Products GmbH
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90431 Nürnberg
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CE0197

Teltow, 2024-03-18

Ort, Datum / Place, Date / Lieu, Date / Luogo, Data

Gültigkeit / Validity / Validité / Validità: 5 Jahre / Years / Années / Anni

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i. A. Dr. Bert Schadow, Regulatory Affairs Manager
Name und Funktion / Name and function / Nom et fonction / Nome e funzione