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:	HeartX Recorder
SRN:	DE-MF-000012384
Basic UDI-DI:	0425090320274NK
REF:	86100-IEM
Klasse / class / classe:	IIa

Intended Purpose:

The device is intended to continuously record up to 3-channel ECG data. The recorded data is downloaded for analysis and subsequent evaluation by a trained physician or healthcare professional. Patients include pediatrics weighing less than 10 kg, children and adults in home environments, hospitals or hospital-like facilities. The device is suitable for patients who may benefit from long-term continuous electrocardiographic recording, including, but not limited to, patients with conditions such as palpitations, syncope, chest pain, shortness of breath, or patients who need to be monitored to assess current cardiac function. The device is not intended for use as a critical care monitoring system and must not be used in emergency situations.

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 GSPR Dokument 2222-TD-0004-00-General Safety and Performance Requirements.

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 GSPR list 2222-TD-0004-00-General Safety and Performance Requirements.

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 pour la liste GSPR de l'appareil 2222-TD-0004-00-General Safety and Performance Requirements.

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 in relazione all'elenco GSPR del dispositivo 2222-TD-0004-00-General Safety and Performance Requirements.

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
Tillystraße 2
90431 Nürnberg
Deutschland / Germany / Allemagne / Germania
CE0197

Teltow, 2025-04-16

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