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 Docking Station
SRN:	DE-MF-000012384
Basic UDI-DI:	0425090320276NP
REF:	86150
Klasse / class / classe:	I

Intended Purpose:

The HeartX Recorder Docking Station is used to charge the HeartX Recorder device and transfer recorded ECG data. The HeartX Recorder Docking Station ensures a stable connection for reliable data transfers via USB, while simultaneously charging the HeartX Recorder device to keep it ready for use.

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 II, III, IV
Conformity assessment procedure: /	Regulation (EU) 2017/745 Annex II, III, IV
Procédure d'évaluation de la conformité: /	Règlement (UE) 2017/745 Annexe II, III, IV
Procedura di valutazione della conformità:	Regolamento (UE) 2017/745 Allegato II, III, IV

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Teltow, 2025-04-17

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

i. A. Dr. Bert Schadow, Regulatory Affairs Manager

Name und Funktion / Name and function / Nom et fonction / Nome e funzione

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