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:	PhysioMem PM 100 4G
SRN:	DE-MF-000012384
Basic UDI-DI:	0425090320243N8
REF:	77214001
Klasse / class / classe:	IIa

Intended Purpose:

The PM 100 device is a two-channel cardiac event recorder for transmitting multiple event recordings via cellular telephony networks to a compatible receiving system, such as ReSTA from GETEMED. The device is intended for patient activated recordings. The PM 100 is intended to be used in both home environments and clinical environments. Home environments include urban/suburban/ rural, school/office/retail environments, and vehicles like trains and cars. Airplanes are excluded as long as the use of cellular radio equipment is not allowed during flight. The device is battery-driven and utilizes a FLASH memory to store ECG data. The PM 100 is not intended to be used as a critical care monitoring system and should 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 zum Produkt gehörigen Endprüfprotokoll (DHR).

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 final inspection report (DHR) of the device.

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 si elle est associée au rapport de l'inspection finale (DHR) du produit.

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. Questa dichiarazione è valida in congiunzione con il rapporto di ispezione finale (DHR) del prodotto..

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
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Teltow, 2023-07-05

getemed
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E-Mail: info@getemed.de

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