Business Stream Products
Certification Body

TÜVRheinland®
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TÜV Rheinland LGA Products GmbH · 90431 Nürnberg

Customer Service Center
for Products
Tel. +49 911 655-5225
Mail service@de.tuv.com

Date: November 17, 2020

Mr. James Frett
GE Medical Systems
Information Technologies, Inc.
9900 Innovation Drive
WAUWATOSA, WI 53226
USA

Application for : **QMS**
Certificate No. : HZ 2214580-1
Device : Only for QM-System audit
Test requirement : REGULATION (EU) 2017/745 on Medical Devices
Annex IX Chapter 1, Section 2 and 3 and Chapter III

Dear Mr. Frett:

Your Quality Management System has been evaluated.
The conformity assessment activities included also the assessment of the technical documentation DOC2343355, revision 1, dated 2020-08-18 for the product Unity Network ID [V10].
In order to substantiate the certification decision it is necessary to confirm the classification under REGULATION (EU) 2017/745 on Medical Devices for the above mentioned medical device.
Therefore the certification decision is conditionally (see below).
Enclosed please find the certificate
No. HZ 2214580-1

Conditions:
Please send meaningful documents issued by a European competent authority until May 17, 2021 to substantiate the defined classification by the manufacturer for the above mentioned device.

Digitally signed by Ceaicovschi Tudor
Date: 2024.07.18 16:59:11 EEST
Reason: MoldSign Signature
Location: Moldova

Best regards,

Certification Body

Song Liu

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EC Certificate

EU 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 2214580-1
Manufacturer:	**GE Medical Systems Information Technologies, Inc.** 9900 Innovation Drive Wauwatosa, WI 53226 USA
EUDAMED Single Registration No.:	N/A
Products:	Class IIa- Z120503 ELECTROCARDIOGRAPHS Class IIb -Z120302 VITAL SIGNS MONITORING INSTRUMENTS
Authorised representative(s):	**GE Medical Systems SCS** 283 Rue de la Miniere, 78530 BUC France

Certificate history		
Revision:	Description:	Issue date:
0	Initial	2020-11-17

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.:	234158038-30
Effective date:	2020-11-17
Expiry date:	2025-10-30
Issue date:	2020-11-17

TÜV Rheinland Product Safety GmbH Zertifizierungsstelle TÜVRheinland®

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

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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.

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