GE Healthcare

EU DECLARATION OF CONFORMITY

Following the provisions of the medical devices regulation 2017/745.

Following the provisions of the RoHS directive 2011/65/EU.

We:

Legal Manufacturer	EU Authorized Representative
GE Medical Systems Information Technologies, Inc. 9900 Innovation Drive Wauwatosa, WI 53226 USA	GE Medical Systems SCS 283 rue de la Minière 78530 BUC, France

Manufacturing Sites

Wipro GE Healthcare Private Limited
No.4, Kadugodi Industrial Area
Bangalore 560067,
Karnataka, India

GE Healthcare Finland OY
Kuortaneenkatu 2
Helsinki, FIN-00510, Finland

Declare under our sole responsibility that the device:

MAC 600

Basic UDI-DI:
8406821BUG00169HM

Digitally signed by Chicu Natalia
Date: 2023.07.03 13:18:29 EEST
Reason: MoldSign Signature
Location: Moldova

Date: 18 Nov 2021

Wauwatosa, WI, USA

Lee Bush
Director Regulatory Affairs

Reference of the Declaration: DOC2525300

Intended Purpose:

The MAC 600 Resting ECG Analysis System is intended to acquire, analyze, display, and record electrocardiographic information for adult and pediatric populations.

Basic systems deliver 3 or 12 lead ECGs and can be upgraded to provide software analysis options such as interpretive analysis of the electrocardiogram.

Transmission of ECG data to a central ECG cardiovascular information system is optional.

The MAC 600 is intended to be used by trained operators in a hospital or medical professional's facility environment as well as used in clinics, physician offices, outreach centers or wherever ECG testing is performed to record ECG signals from surface electrodes.

GMDN Code and Description:
16231 - Electrocardiograph, professional, multichannel

Class: IIa

Classification rule (Annex VIII): 10

to which this declaration relates is in conformity with the requirements of the Medical Devices Regulation 2017/745 that apply to it, RoHS directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment, Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 concerning waste of electrical and electronic equipment (WEEE), and Directive 80/181/EEC on the approximation of the laws of the Member States relating to units of measurement.

This conformity is based on the following elements:

Technical Documentation reference: DOC2553974, of the product to which this declaration relates.

EU certificate No. HZ 2214580-1:

- Conformity assessment procedure followed: Annex IX, Chapter I, Section 2 and 3 and Chapter III
- Delivered by TÜV Rheinland LGA Products GmbH (0197)

End of Document

Date: 18 Nov 2021

Wauwatosa, WI, USA

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