GE HealthCare

EU DECLARATION OF CONFORMITY

Following the provisions of the Medical Devices' Regulation 2017/745
and of the Directive 2011/65/EU on RoHS

We:

Manufacturer	EU Authorized Representative
GE Medical Systems Information Technologies, Inc. **9900 Innovation Drive** **Wauwatosa, WI 53226, USA** Single Registration Number (SRN): **US-MF-000017529**	**GE Medical Systems SCS** **283 rue de la Minière** **78530 BUC, France** SRN: **FR-AR-000000344**

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:

Product Name	**MAC 600** **Resting ECG Analysis System**
Identification/ REF	**2048726-001**
Intended Purpose	The MAC 600 Resting ECG Analysis System is intended to acquire, analyse, display, and record electrocardiographic information for adult and paediatric 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 centres or wherever ECG testing is performed to record ECG signals from surface electrodes.
BASIC UDI-DI	**8406821BUG00169HM**
UDI-DI (GTIN)	**00840682134859**
EMDN Code	**Z120503** **Electrocardiographs**
GMDN Code	**16231** **Electrocardiograph, professional, multichannel**
Device Class	**IIa**
Classification Rule (Annex VIII)	**Rule 10**

SIGNATURE:

Date of issue: 08-May-2023
Place of issue: Wauwatosa, Wisconsin, USA
Name: Shlomi Deler
Function: Director, Regulatory Affairs

Signature: 

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To which this declaration relates is in conformity with the requirements of the medical devices regulation 2017/745 that apply to it, with the requirements of the RoHS directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment and with the requirements of Commission Regulation (EU) No 207/2012 of 9 March 2012 on electronic instructions for use of medical devices, as applicable.

This conformity is based on the following elements:

- Technical Documentation reference: **DOC2553974**, of the product to which this declaration relates.
- ISO13485:2016: Approval of Quality Management System delivered by TUV Rheinland, Germany/ Certificate N **SX 60146867 0001**
- EC certificate N: **HZ 2214580-1**
  - Conformity assessment procedure followed: Annex IX, Conformity Assessment Based on a Quality Management System and on Assessment of Technical Documentation
  - Delivered by TUV Rheinland (0197)
- List of applicable Standards: Refer to General Safety and Performance Requirement: **DOC2506623**

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