EU DECLARATION OF CONFORMITY

Following the provisions of the medical devices regulation 2017/745

ROHS directive 2011/65/EU and Radio Equipment Directive 2014/53/EU.

We:

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

Manufacturing Site

Manufacturing Facility 1

GE Medical Systems (China)Co., Ltd

No.19 Changjiang Road, Wuxi National Hi-Tech Development Zone
Jiangsu, 214028, China

Manufacturing Facility 2

GE Medical Systems Information Technologies

CRITIKON DE MEXICO S. de R.L. de C.V.

Calle Valle del Cedro 1551- Juarez- 32575 CHIHUAHUA-MEXICO

Declare under our sole responsibility that the device:

MAC 5 A4/ MAC 5 A5/ MAC 5 Lite Resting ECG Analysis System

Basic UDI-DI: 8406821BUG00244HA

Model Identification/GTIN Numbers:

Model	Identification Number	GTIN Number
MAC 5 A4	8855001-001	00195278276070
MAC 5 A5	8855002-001	00195278276124
MAC 5 Lite	8855003-001	00195278276087

Intended Purpose:

The MAC 5 A4/ MAC 5 A5/ MAC 5 Lite Resting ECG Analysis System is intended to acquire, analyze, display, and record electrocardiographic information from adult or pediatric populations. Basic system delivers 3, 6, or 12 lead ECG's and interpretive analysis. Transmission and reception of ECG data and other clinical data to and from a central clinical information system is optional.

The MAC 5 A4/ MAC 5 A5/ MAC 5 Lite Resting ECG Analysis System is intended to be used under the direct supervision of a licensed healthcare practitioner, by trained operators in a hospital, medical professional's facility or wherever ECG testing is performed.

GMDN Code and description: 16231, Interpretive multichannel electrocardiograph

EMDN Code and description: Z120503, Electrocardiographs

Class: IIa

Classification rule (Annex VIII): Rule 10

SIGNATURE:

15-Feb-2022

Lee Bush
Director, Regulatory Affairs
Wauwatosa, WI

Date

To which this declaration relates is in conformity with the requirements of the medical devices regulation 2017/745 that apply to it. In addition, the product is in conformity with the requirements of the directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (as assessed by the manufacturer)

This conformity is based on the following elements:

- Technical Documentation reference DOC2617643, of the product to which this declaration relates.
- EC certificate N HZ 2214580-1:
  - Conformity assessment procedure followed: Annex IX, Chapters I, III
  - Delivered by TÜV Rheinland LGA Products GmbH (0197)
- List of applicable Standards: Refer to General Safety and Performance Requirement (DOC2272151)

We, manufacturer, declare under our sole responsibility that:

MAC 5 A4/ MAC 5 A5/ MAC 5 Lite Resting ECG Analysis System equipped with TI WL18x7MOD WLAN module

To which this declaration relates is in conformity with the requirements of the Radio Equipment Directive 2014/53/EU which applies to it.

This conformity is based on the following elements:

- The device conforms to the Directive 2014/53/EU through Annex II-Internal Production Control.
- List of standards applied : Refer to General Safety and Performance Requirement (DOC2272151)

SIGNATURE:

15-Feb-2022

Lee Bush
Director, Regulatory Affairs
Wauwatosa, WI

Date

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