EU DECLARATION OF CONFORMITY

Following the provisions of the medical devices regulation 2017/745 and of the directive 2011/65/EU

We:

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

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 7 *Resting ECG Analysis System*

Basic UDI-DI: 8406821BUG00013GM

GTIN No: 00840682144322

Intended Purpose:

The MAC 7 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 7 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.

EMDN Code: Z120503, Electrocardiographs

EMDN Description: Electrocardiographs

Class: IIa

Classification rule (Annex VIII): Rule 10

SIGNATURE:

25-Nov-2020

Lee Bush
Director, Regulatory Affairs,
Wauwatosa, WI, USA

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 DOC2373866, 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, Chapters I, III
  - Delivered by TUV Rheinland (0197)
- List of applicable Standards: Refer to General Safety and Performance Requirement (DOC1935348)

We, manufacturer, declare under our sole responsibility that:

MAC 7 Resting ECG Analysis System equipped with wl1837 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 : **Annexure 1**

SIGNATURE:

25-Nov-2020

Lee Bush
Director, Regulatory Affairs,
Wauwatosa, WI, USA

Date

Annexure 1

Relevant Standards/ *relevante normen*
EN 300 328 V2.2.2 Wideband transmission systems;Data transmission equipment operating in the 2.4GHz ISM band and using wideband modulation techniques;Harmonised Standaed covering the essential requirements of article 3.2 of Directive 2014/53/EU
EN 301 893 V2.1.1 5 GHz RLAN; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU
EN 301 489-1 V2.2.3 ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU and the essential requirements of article 6 of Directive 2014/30/EU
EN 301 489-17 V3.2.2 ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for Broadband Data Transmission Systems; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU
EN 62311:2008 Assessment of electronic and electrical equipment related to human exposure restrictions for electromagnetic fields (0 Hz - 300 GHz)
EN 60601-1-2:2015 Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic disturbances — Requirements and tests
EN 60601-1:2006/A1:2013 Medical electrical equipment Part 1: General requirements for basic safety and essential performance

End of Document