

Electronic Signature Information

Name	DOC2694340
Revision	1
Type	Controlled Document
Title	MAC 3 Declaration of Conformity
Originator	212421792_gangadhar__ippili
Release Date	12/05/2025 12:54:15 PM
Obsolete Date	

File Name	File Description	File Size (Bytes)
MAC 3 Declaration of Conformity.pdf		256549

Route	Signer	Function	Status	Comments	Completion Date
R-11670636	100035647_shlomi__deler		Approve	Approved as a Task Assignee	5 Dec 2025 12:54:16 GMT

Periodic Review

There are no signatures or routes related to this business object.
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Obsolesence Approval

There are no signatures or routes related to this business object.
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EU DECLARATION OF CONFORMITY

Following the provisions of the Medical Devices' Regulation 2017/745
and of the Directive 2015/863/EU on RoHS and Radio Equipment Directive 2014/53/EU

We:

Manufacturer

GE Medical Systems Information Technologies, Inc.
3114 N Grandview Blvd,
Waukesha, WI 53188
Single Registration Number (SRN): **US-MF-000017529**

EU Authorized Representative

GE Medical Systems SCS
283 rue de la Minière
78530 BUC, France
SRN: **FR-AR-000000344**

Manufacturing Site

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

Declare under our sole responsibility that the devices:

Product Name	MAC 3
BASIC UDI-DI	08406821BUG0050573
Identification/ REF	3048726-001
UDI-DI (GTIN)	00195278921628
EMDN Code	Z120503 Electrocardiographs
GMDN Code	16231 Electrocardiograph, professional, multichannel
Device Class	Ila
Classification Rule (Annex VIII)	Rule 10

Intended Use:

The MAC 3 Resting ECG Analysis System is intended to acquire, analyze, display, and record electrocardiographic information for adult and pediatric populations.

Basic system delivers 3, 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 3 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.

SIGNATURE:

Date of issue: **12-December-2025**

Place of issue: **Waukesha, Wisconsin, USA**

Name: **Shlomi Deler**

Function: **Director, Regulatory Affairs**

Signature: _____



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 2015/863/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: **DOC2694338**, of the product to which this declaration relates.
- ISO13485:2016: Approval of Quality Management System delivered by TUV Rheinland, Germany/ Certificate: **SX 2214580-1**
- EC certificate: **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: **DOC2729182**

We, manufacturer, declare under our sole responsibility that: MAC 3

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 on Radio Equipment - full DoC found within **DOC3214113**
- Essential Principles Conformity Record, **DOC2729182**, contains the list of harmonized standards applied.

SIGNATURE:

Date of issue: **12-December-2025**

Place of issue: **Waukesha, Wisconsin, USA**

Name: **Shlomi Deler**

Function: **Director, Regulatory Affairs**

Signature:  _____