

EC DECLARATION OF CONFORMITY

Following the provisions of the medical devices directive 93/42/EEC
and of the directive 2011/65/EU.

EG-KONFORMITÄTSERKLÄRUNG

Entsprechend der Anforderung der Medizin Produkte Richtlinie 93/42/EEC,
und der Richtlinie 2011/65/EU.

We/ Wir

Manufacturer
Hersteller

**GE Medical Systems
Information Technologies, Inc.
8200 West Tower Avenue
Milwaukee, WI 53223, USA**

EU Authorized Representative
Autorisierter EU-Vertreter

**GE Medical Systems
Information Technologies GmbH
Munzingerstrasse 5
79111 Freiburg, Germany**

Manufacturing site (if different from manufacturer)
Fertigungsstätte (falls anders als Hersteller)

**GE Medical systems (China) Co., Ltd
No. 19, ChangJiang Road, WuXi National Hi-tech Development Zone ,
Jiangsu, P.R.China 214028**

Declare under our sole responsibility that the class IIa device:
Erklären unter unserer alleinigen Verantwortung, dass das Produkt der Klasse IIa:

MAC 800 Resting ECG Analysis System

Ref. see addendum/ oder siehe Anhang

GMDN Code: **16231**

Classification rule (93/42/EC Annex IX) / Klassifizierungsregel (93/42/EWG Anhang IX) : **Rule 10**

To which this declaration relates, is in conformity with the requirements of the medical devices
directive 93/42/EEC which apply to it and with the requirements of the directive 2011/65/EU on the
restriction of the use of certain hazardous substances in electrical and electronic equipment

*Diese Erklärung bezieht sich auf die Konformität mit den grundlegenden Anforderungen der Medizin
Produkte Richtlinie 93/42/EEC und mit den Anforderungen der Richtlinie 2011/65/EU zur Beschränkung
der Verwendung bestimmter gefährlicher Stoffe in Elektro- und Elektronikgeräten.*

This conformity is based on the following elements:

Diese Konformität basiert auf den folgenden Elementen:

- Information included in the documents:
Design History File Ref.: DOC0775805, of the product to which this declaration relates.

30th November-2018

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Morrison, Monica
Senior Regulatory Affairs Director

CE-M-150 DOC0519258

Informationen, die in diesen Dokumenten enthalten sind:

Entwicklungsverlaufsdatei Ref./réf.: DOC0775805, des Produkts, auf das sich diese Erklärung bezieht.

- EC certificate: approval of full quality assurance system (Annex II of the medical devices directive 93/42 EEC) delivered by <GMED> (Notified Body #0459) on under Certificate N° 7550. The medical device bears the mark



EG-Zertifikat: Genehmigung des kompletten Qualitätssicherungssystems (Anhang II der Richtlinie 93/42/EWG über Medizinprodukte), ausgestellt von <GMED> (Benannte Stelle #0459) am unter Zertifikat Nr. 7550.

- List of harmonized standards applied for CE marking
Liste der harmonisierten Normen, die für die CE-Kennzeichnung angewendet wurden

EN 60601-1:2006 Medical Electrical Equipment- Part 1: General Requirements for Safety.

EN 60601-1-2:2007 Medical electrical equipment – Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Capability.

IEC 60601-2-25:2011 Medical Electrical Equipment-Part 2-25: Particular requirements for the safety of electrocardiographs .

EN 60601-1-6:2010 Medical Electrical Equipment – Part 1-6: General Requirements for Safety – Collateral Standard: Usability

EN 62304:2006 Medical device software - Software life-cycle processes

EN 62366:2008 Medical devices - Application of usability engineering to medical devices

EN 1041:2008 Information supplied by the manufacturer with medical devices

EN ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements

This EC declaration of conformity supersedes the previous declaration dated 23-July-2018
Diese EG-Konformitätserklärung ersetzt die vorherige Erklärung mit Datum vom 23.Juli.2018

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ADDENDUM TO THE EC DECLARATION OF CONFORMITY
ERGÄNZUNG ZUR KONFORMITÄTSERKLÄRUNG

Product Description <i>Produktbezeichnung</i>	Catalog Designation <i>Katalogbezeichnung</i>
MAC 800 Resting ECG Analysis System	2061354-001
MAC800 Generic ATO Model Upgrade	2065552-001
MAC800 Software Upgrade Kit ATO OC	2067328-001
<u>Accessories / Options:</u> <u>Zubehör / Optionen:</u>	
Part #	Component Description
Patient Cable	
2029890-001	MAC500/1200 VALUE 10LD CABLE/LDWR IEC
2029893-001	MAC500/MAC1200 VALUE 10LD CABLE AHA
22341808	CABLE TRUNK 10-LEAD ML IEC
420101-002	CAM 14 ECG Leadwire Set, Universal, mixed length, 10/set
22341809	CABLE TRUNK 10-LEAD ML AHA
900178-001	CAM 14 ECG Connector Set, Banana, 10/set, AHA
900178-101	CAM 14 ECG Connector Set, Banana, 10/set, IEC
2104722-001	Trunk Cable 10-Lead IEC
2104723-001	Trunk Cable 10-Lead AHA
2104724-002	Leadwire Set, Base 10, DCAR, Banana, IEC
2104724-001	Leadwire Set, Base 10, DCAR, Banana, AHA
2104726-001	ECG VALUE CABLE 10 LEAD CABLE/LDWR IEC
2104727-001	ECG VALUE CABLE 10 LEAD CABLE/LDWR AHA
2104729-001	Adapter Clip, DCAR, Wide Mouth Clip, 14 pack
Electrodes	
2029891-001	CLAMP LIMB IEC VALUE 4/SET BOXED W/LBL
2029894-001	CLAMP LIMB AHA VALUE 4/SET BOXED W/LBL
2029892-001	REUSABLE BULB ELECTR 6/SET BOXED W/LBL
9623-810P	Silver Mactrode Plus Resting ECG Electrodes, 10/card, 100/pack, 1000/case
2066867-010	ECG CLIP, MACTRODE, 10/PKG
2066867-014	ECG CLIP, MACTRODE, 14/PKG
2056813-010	ECG CLIP, SURE-LOCK, 10/PKG
402207-810	BABYMAC ELECTRODE 10L 50CD
2104778-001	ECG TAB ELECTODE SM HYDROGEL ADHESIVE 10/STRIP 100/POUCH 1000/BOX 4000/CASE
2106911-001	ECG TAB ELECTRODE MED HYDROGEL ADHESIVE 10/STRIP 100/POUCH 1000/BOX 4000/CASE
2104780-001	ECG TAB ELECTRODE LG HYDROGEL ADHESIVE 10/STRIP 100/POUCH 1000/BOX 4000/CASE
2104778-001	ECG TAB ELECTODE SM HYDROGEL ADHESIVE 10/STRIP 100/POUCH 1000/BOX 4000/CASE

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2106911-001	ECG TAB ELECTRODE MED HYDROGEL ADHESIVE 10/STRIP 100/POUCH 1000/BOX 4000/CASE
2104780-001	ECG TAB ELECTRODE LG HYDROGEL ADHESIVE 10/STRIP 100/POUCH 1000/BOX 4000/CASE
2104783-001	Reusable Value Bulb Electrode 6/set
2104784-001	Clamp Limb AHA Value 4/set
2104785-001	Clamp Limb IEC Value 4/set
Cream	
21708318	Electrode Cream, 250ml bottle
21730701	Electrode Contact Spray, 200ml bottle
Paper	
2036970-001	PAPER THRM 110X140 CONTR F-GRID 10X200SH
2104775-001	PAPER 110MM WIDE, RED GRID 100MM WIDE, Z- FOLD, BLOCK QUEUE, 200 SHEETS, 10 PACKS
2104775-001	PAPER 110MM WIDE, RED GRID 100MM WIDE, Z- FOLD, BLOCK QUEUE, 200 SHEETS, 10 PACKS
Trolley	
2056556-001	MAC COMPACT TROLLEY
2064414-001	SIMPLE ARM AND BARCODE KIT FOR COMPACT TROLLEY
2062354-001	PRINTER SHELF ASSEMBLY COMPACT TROLLEY

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