EC DECLARATION OF CONFORMITY

TF – DOC1979924 (CE-M-213)
Following the provisions of the medical devices directive 93/42/EEC, Annex II and of the directive 2011/65/EU.

EG-KONFORMITÄTSERKLÄRUNG

Gemäß den Vorschriften der Richtlinie 93/42/EWG über Medizinprodukte, Anhang II 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
Herstellung Standort

Critikon de Mexico S. de R.L. de C.V.
Calle Valle del Cedro 1551
Juarez Mexico 32575

Distribution Site
Verteilung Standort

GE Medical Systems Information Technologies, Inc.
465 Pan American Drive
Suite 11
El Paso, TX 79907 USA

Declare under our sole responsibility that the class **IIa** medical device:
*Erklären unter alleiniger Verantwortung, dass das Medizinprodukt der Klasse **IIa**:*

MAC VU360 Resting ECG Analysis System

(including system components and GE accessories/einschließlich Systemkomponenten und GE Zubehör)

Ref. : see addendum/ *oder siehe Anhang*

GMDN Code: 16231

UMDNS Code: 11-411

Classification rule (93/42/EC Annex IX) / *Klassifizierungsregel (93/42/EG 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.
Auf das sich diese Erklärung bezieht, den Anforderungen der Richtlinie 93/42/EWG über Medizinprodukte, die für das Produkt gelten, und den Anforderungen der Richtlinie 2011/65/EU zur Beschränkung der Verwendung bestimmter gefährlicher Stoffe in Elektro- und Elektronikgeräten entspricht.

Milwaukee, USA, 16-March-2018
Milwaukee, USA, 16-März.2018

Douglas Kentz
Regulatory Affairs Director

This medical device conformity is based on the following elements:
Diese Medizinprodukte Konformität basiert auf den folgenden Elementen:

- Information included in the documents:
  Technical Documentation/DHF Ref./ réf: **DOC1570066**, of the product to which this declaration relates.
  Informationen, die in den Dokumenten enthalten sind:
  Technische Dokumentation/DHF-Ref./réf: **DOC1570066,** 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) issued by LNE/G-MED France, (NB #0459) Certificate No. 7550 (DOC0279260).
  EG-Zertifikat: Genehmigung des kompletten Qualitätssicherungssystems (Anhang II der Richtlinie 93/42/EWG über Medizinprodukte), ausgestellt von G-MED France, NB #0459 / *Zertifikat Nr.* 7550 (DOC0279260).

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

1. **Council Directive 93/42/EEC** of 14 June 1993 concerning medical devices
2. **EN ISO 13485:2003, 2012** Quality systems - Medical devices - Quality management systems - Requirements for regulatory purposes
3. **EN ISO 14971:2012** Medical devices - Application of risk management to medical devices
4. **EN 60601-1:1990/A1:1993/A2:1995/A13:1996** Medical Electrical Equipment - Part1: General Requirements for Safety equipment -- Part 1: General requirements for safety. Collateral standard: Safety requirements for medical electrical systems
5. **EN 60601-1:2006/AC:2010** Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Essential Performance
6. **EN 60601-1-2:2007/AC:2010** Medical Electrical Equipment – Part 1-2: General Requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility - Requirements and tests
7. **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
8. **EN 60601-1-4:1996/A1:1999** Medical Electrical Equipment - Part 1-4: General Requirements for Safety - Collateral standard: Programmable Electrical Medical Systems.
9. **EN 60601-1-6:2010** Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
10. **EN 60601-2-25:1995, +A1:1999, 2011** Medical Electrical Equipment - Part 2-25: Particular requirements for basic safety and essential performance of electrocardiographs
11. **EN 60601-2-51:2003** Medical Electrical Equipment – Part 2-51: Particular requirements for safety, including essential performance, of recording and analysing single channel and multichannel electrocardiographs
12. **EN 62304:2006/AC:2008** Medical device software - Software life-cycle processes
13. **EN 62366:2008** Medical devices - Application of usability engineering to medical devices
14. **EN 15223-1:2016** Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied

This EC declaration of conformity supersedes the previous declaration: None, initial release
Diese EG-Konformitätserklärung ersetzt die vorherige Erklärung: Keine, Initiale Freisetzung

Milwaukee, USA, 16-March-2018
Milwaukee, USA, 16-März.2018

Douglas Kentz
Regulatory Affairs Director

ADDENDUM TO THE EC DECLARATION OF CONFORMITY
ERGÄNZUNG ZUR KONFORMITÄTSERKLÄRUNG

Product Description ***Produktbezeichnung***	**Catalog Designation** ***Katalogbezeichnung***
MAC VU360	2030360-001
MAC VU360 UPGRADE	2030361-001
CAM CONNECT 14 WITH BARCODE	2091685-001
CAM CONNECT 14	2091686-001
MAC VU360 KISS SYSTEM	2104307-001
MAC VU360 EXTRA BATTERY	2036984-001
MAC VU360 BATTERY CHARGER	2083287-001
CABLE ASSY, TRUNK, CAM CC14	2088554-001
KIT LEADWIRE BLANK PLUG	2001926-001
KIT AM4 LEADWIRE SEPARATOR	401089-003
BATTERY CHARGER WITH AUSTRALIA POWER CORD	2083292-002
BATTERY CHARGER WITH BRITISH POWER CORD	2083292-003
BATTERY CHARGER WITH CONT EUROPE POWER CORD	2083292-004
BATTERY CHARGER WITH ISRAEL POWER CORD	2083292-006
BATTERY CHARGER WITH ITALY POWER CORD	2083292-007
BATTERY CHARGER WITH SWISS POWER CORD	2083292-009
BATTERY CHARGER WITH DENMARK POWER CORD	2083292-010
BATTERY CHARGER WITH CHINA POWER CORD	2083292-013
BATTERY CHARGER WITH INDIA POWER CORD	2083292-015

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Milwaukee, USA, 16-März.2018

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Regulatory Affairs Director