EC DECLARATION OF CONFORMITY

TF – DOC0077948 (CE-M-098)
Following the provisions of the medical device 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
Munzinger Straße 5
79111 Freiburg, Germany

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

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

GE Healthcare Finland Oy
Kuortaneenkatu 2
00510 Helsinki , Finland

GE Medical Systems Information Technologies
456 Pan American Drive, Suite 11
El Paso, Texas 79907, USA

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

Digitally signed by Chicu
Date: 2024.01.29 10:21:32
Reason: MoldSign Signatu
Location: Moldova

CardioSoft Cardiac Testing System
Including system components and accessories/einschließlich Systemkomponenten und Zubehor)

Ref. : see addendum/ *oder siehe Anhang*

GMDN Code: 36145

UMDNS Code: 17-723

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 device 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.

Lee Bush
Director, Regulatory Affairs

Milwaukee, USA, 12.April.2019

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: **DOC0410162**, of the product to which this declaration relates.
  Informationen, die in den Dokumenten enthalten sind:
  Technische Dokumentation/DHF-Ref./réf: **DOC0410162** 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 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. **EN ISO 13485:2016** Medical devices -- Quality management systems -- Requirements for regulatory purposes
2. **EN ISO 14971:2012** Medical Devices – Application of Risk Management to Medical Devices
3. **EN 60601-1:1990, A1:1993, A2:1995, A13:1996,** Medical Electrical Equipment Part 1: General Requirements for Safety
4. **EN 60601-1:2012** Medical electrical equipment – Part 1: General Requirements for Basic Safety and Essential Performance
5. **EN 60601-1-1:2001** Medical electrical equipment – Part 1-1: General requirements for safety Collateral standard: Safety requirements for medical electrical systems
6. **EN 60601-1-2:2007/AC:2010** Medical electrical equipment – Part 1-2: General requirements for safety Collateral standard: Electromagnetic compatibility Requirements and tests
7. **EN 60601-1-2:2015** Medical electrical equipment – Part 1-2: General requirements for 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 62304:2006** Medical device software-Software life-cycle processes
10. **EN 62366:2008** Medical devices - Application of usability engineering to medical devices
11. **EN 60601-1-6:2007** Medical electrical equipment - Part 1-6: General requirements for safety - Collateral standard: Usability
12. **EN 60601-2-25:1995, A1:1999** Medical Electrical Equipment – Part 2-25: Particular Requirements for the Safety of Electrocardiographs
13. **EN 60601-2-25:2011** Medical electrical equipment – Part 2-25: Particular requirements for the basic safety and essential performance of Electrocardiographs
14. **EN 60601-2-51:2003** Medical electrical equipment -- Part 2-51: Particular requirements for safety, including essential performance, of recording and analyzing single channel and multichannel electrocardiographs
15. **EN 1041:2008+A1:2013** Information supplied by the manufacturer with medical devices
16. **EN ISO 15223-1:2016** Symbols for use in the labeling of medical devices
17. **EN ISO 10993-1:2009/AC:2010** Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
18. **EN ISO 10993-5:2009** Biological Evaluation of Medical Devices - Part 5: Test For In Vitro Cytotoxicity

This EC declaration of conformity supersedes the previous declaration dated 14-March-2019

Lee Bush
Director, Regulatory Affairs

Milwaukee, USA, 12.April.2019

Diese EG-Konformitätserklärung ersetzt die vorherige Erklärung mit Datum vom 14.März.2019

Lee Bush

Milwaukee, USA, 12.April.2019

Director, Regulatory Affairs

ADDENDUM TO THE EC DECLARATION OF CONFORMITY
ERGÄNZUNG ZUR KONFORMITÄTSERKLÄRUNG

Product Description ***Produktbezeichnung***	**Catalog Designation** ***Katalogbezeichnung***
CardioSoft v6.7 CD	2006301-044
CardioSoftv6.7 Software	2006300-101
Options:	**Part Number:**
CardioSoft ECG Analysis System V6.7 Generic ATO Model	2060450-001
CSOFT-CS V6.7 CLIENT GENERIC ATO MODEL	2060452-001
CSOFT ECG VIEWER V6.7 GENERIC ATO MODEL	2060451-001
CAM-USB Interface Box V2 , required for the CAM-14 acquisition module	2040437-001
CAM-USB A/T Interface Box V2	2040438-001
CAM-USB A/T KISS Interface Box V2	2040438-009
Software Option:	
Resting ECG Interpretation (RESI)	45502401
Remote View (ERGM)	45502901
Storage of the Full-Disclosure ECG (EGMO)	45502701
Data Storage on Network Server, < 3000 tests (NETS)	45503001
Data Storage on Network Server, < 15000 tests (NET2)	2014659-001
Data Storage on Network Server, unlimited numbers of tests (NET3)	2014659-002
Arrhythmia Detection / Documentation (ARRY)	2014659-014
2D Waterfall Display (2DWF)	2014659-003
MUSE Browser (BRWS)	2014659-004
Risk Factors (RISK)	2014659-005
Data Export (EXPD)	2014659-006
Report Export as PDF File (EPDF)	2014659-007
Report Export as Word File (EWRD)	2014659-008
Display Configuration (DSPC)	2014659-009
In-Test Tabular Summary (ITBL)	2014659-010
In-Test Trend (ITRD)	2014659-011
Previous Test Retrieval (PRVT)	2014659-012
T-Wave Alternans (TWAA)	2014659-013
EMR Interface (XEMR)	2014659-020
Floating License (FLLX)	2014659-021
Resting ECG Measurement (RESM)	45502301
ST Measurement, Arrhythmia, 6/12-Lead Exercise Test (ERG2)	45502601
Exercise Test Expert Mode (ERG3)	45503201
CardioSoft Web (CWEB)	45505101
ECG History (ECGH)	45504001
DICOM interface (DICM)	2014659-026
ST/HR Hysteresis (STHY)	2014659-028
Exercise Test Interpretation (EXTI)	2014659-029

Lee Bush
Director, Regulatory Affairs

Milwaukee, USA, 12.April.2019