EC DECLARATION OF CONFORMITY

TF – DOC0095068 (CE-M-129)
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 (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

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

T2100 Treadmill

Part Numbers: 2065453-001

GMDN Code: 36679

UMDNS Code: 14-141

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.

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, 01-Sep-2017
Milwaukee, USA, 01.Sep.2017

Douglas Kent
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: **DOC0423188**, of the product to which this declaration relates.
  Informationen, die in den Dokumenten enthalten sind:
  Technische Dokumentation/DHF-Ref./réf: **DOC0423188** 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) on 26-July-2017/ Certificate No. 7550.
  EG-Zertifikat: Genehmigung des kompletten Qualitätssicherungssystems (Anhang II der Richtlinie 93/42/EWG über Medizinprodukte), ausgestellt von G-MED France, NB #0459 *am* 26-Juli-2017 / *Zertifikat Nr.* 7550.
- 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. **Council Directive 2006/42/EC** of 17 Mai 2006 concerning machinery
3. **EN 60601-1:2006/A1: 2013**, Medical Electrical Equipment-Part 1: General requirements for basic safety and essential performance
4. **EN60601-1-1:2001**, Medical Electrical Equipment Part 1-1: General Requirements for Safety, Collateral Standard: Safety Requirements for Medical Electrical Systems.
5. **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
6. **EN 60601-1-4:1996, +A1:1999**, Medical Electrical Equipment - Part 1-4: General Requirements for Safety - Collateral Standard: Programmable Electrical Medical Systems
7. **EN 60601-1-6:2010**, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability
8. **EN 62304:2006/AC:2008**, Medical device software – software life-cycle processes
9. **EN 62366:2008**, Medical devices – application of usability engineering to medical devices
10. **EN 980:2008** Symbols for use in the labelling of medical devices
11. **EN 1041:2008**, Information supplied by the manufacturer with medical devices

This EC declaration of conformity supersedes the previous declaration dated 09-June-2016
Diese EG-Konformitätserklärung ersetzt die vorherige Erklärung mit Datum vom 09.Juni.2016

Milwaukee, USA, 01-Sep-2017
Milwaukee, USA, 01.Sep.2017

Douglas Kentz
Regulatory Affairs Director