



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

Port 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**

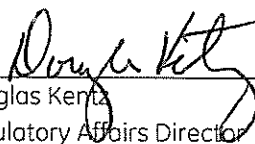
To which this declaration relates, is in conformity with the requirements of the medical devices directive 93/42/EEC which apply to it and with the requirements of the directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

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

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Douglas Kenta
Regulatory Affairs Director

DOC1244248



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

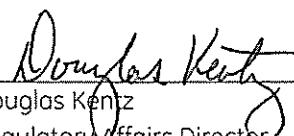
This EC declaration of conformity supersedes the previous declaration dated 09-June-2016

Diese EG-Konformitätserklärung ersetzt die vorherige Erklärung mit Datum vom 09.Juni.2016

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