



## **EC DECLARATION OF CONFORMITY**

**TF – DOC0735209 (CE-M-209)**

Following the provisions of the medical device directive 93/42/EEC, Annex VII

## **EG-KONFORMITÄTSERKLÄRUNG**

Gemäß den Vorschriften der Richtlinie 93/42/EWG über Medizinprodukte, Anhang VII

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 Information Technologies, Inc.  
Critikon de Mexico S. de R.L. de C.V.  
Calle Valle Del Cedro 1551  
Juarez, Chihuahua, Mexico, 32575**

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

**NIBP Air Hoses  
Non-Invasive Blood Pressure Cuff Accessories**

Ref.: See Tables below for detailed List

GMDN Code: 34978 – Cuff, blood pressure, reusable

Classification rule (93/42/EC Annex IX) / *Klassifizierungsregel (93/42/EG Anhang IX) : I*

DOC0735209 Consolidated Technical File Critikon Cuffs

Milwaukee, USA, 13 March 2020

---

Monica Morrison  
Sr. Regulatory Affairs Director

This EC declaration of conformity supersedes the previous declaration dated 11.December.2019



To which this declaration relates, is in conformity with the requirements of the medical devices directive 93/42/EEC which apply to it.

*Auf das sich diese Erklärung bezieht, den Anforderungen der Richtlinie 93/42/EWG über Medizinprodukte, die für das Produkt gelten,*

***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: **DOC0735209**, of the product to which this declaration relates.  
*Informationen, die in den Dokumenten enthalten sind:*  
Technische Dokumentation/DHF-Ref./réf: **DOC0735209** des Produkts, auf das sich diese Erklärung bezieht.

Milwaukee, USA, 13 March 2020

---

Monica Morrison  
Sr. Regulatory Affairs Director

This EC declaration of conformity supersedes the previous declaration dated 11.December.2019



- List of harmonized standards applied for CE marking (Table 1 of 1)  
*Liste der harmonisierten Normen, die für die CE-Kennzeichnung angewendet wurden (Tabelle 1 of 1)*
1. **ISO 13485:2016** Quality systems - 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 1041:2008+A1:2013** Information Supplied by the Manufacturer of Medical Devices
  4. **ISO 10993-1:2009** Biological evaluation of medical devices – Part 1: Evaluating and testing within a risk management system
  5. **EN 80601-2-30:2010+A1:2015** Medical electrical equipment – Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive Sphygmomanometers
  6. **EN ISO 15223-1:2016** Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements
  7. **EN 81060-1:2012** Non-Invasive sphygmomanometers. Part 1 – Requirements and Test Methods for Non-Automated Measurement type.
  8. **EN 1060-3:1997+A1:2005/A2:2009** Non-invasive sphygmomanometers – Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems (section 4, 7.4.1, 7.4.3, 7.5.1, 7.11.3, 9.1, 9.3a, 9.3)
  9. **EN ISO 80369-5:2016** Small-bore connectors for liquids and gases in healthcare applications – Part 5: Connectors for limb cuff inflation applications

Part Number	Description
2058205-001	ASSY CRITIKON HOSE ADLT 2T DINACLICK 3.6M
2058205-002	ASSY CRITIKON HOSE ADLT 2T DINACLICK 7.2M
2058203-001	ASSY CARE HOSE ADLT/PED 2T DINACLICK 1.2M
2058203-002	ASSY CARE HOSE ADLT/PED 2T DINACLICK 3.6M
2058203-003	ASSY CARE HOSE ADLT/PED 2T DINACLICK 7.2M
2087389-001	ASSY CARESCAPE ONE NIBP HOSE ADULT/PED 2T DINACLICK 1.2M
2087389-002	ASSY CARESCAPE ONE NIBP HOSE ADULT/PED 2T DINACLICK 3.6M
2087389-003	ASSY CARESCAPE ONE NIBP HOSE ADULT/PED 2T DINACLICK 7.2M

Milwaukee, USA, 13 March 2020

Monica Morrison  
Sr. Regulatory Affairs Director

This EC declaration of conformity supersedes the previous declaration dated 11.December.2019