



EC DECLARATION OF CONFORMITY

TF – **DOC1430163** (CE-M-201)

Following the provisions of the medical devices directive 93/42/EEC, Annex VII and of the directive 2011/65/EU.

EG-KONFORMITÄTSERKLÄRUNG

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

**Wipro GE Healthcare Private Limited
No. 4, Kadugodi Industrial Area
Bangalore 560067, Karnataka, India**

**GE Healthcare Finland OY
Kuortaneenkatu 2
Helsinki, FIN-00510, Finland**

**GE Healthcare Critikon de Mexico
Calle Valle Del Cedro 1551
Ciudad Juarez, Chihuahua, Mexico, C.P. 32575**

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

**MAC 2000 ECG Analysis System
Electrocardiograph**

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

Ref. : see addendum/ *oder siehe Anhang*

GMDN Code: P 16231

UMDNS Code: 11411

Classification rule (93/42/EC Annex IX) / *Klassifizierungsregel (93/42/EG Anhang IX)* : **Rule 10**

Milwaukee, USA, 6-February-2015
Milwaukee, USA, 6.Februar.2015



Douglas Kentz
Regulatory Affairs Director



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.

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: **DOC0851945**, of the product to which this declaration relates.
Informationen, die in den Dokumenten enthalten sind:
Technische Dokumentation/DHF-Ref./réf: **DOC0851945** 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 14-Jan-2013/ 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 14-Jan-2013 / Zertifikat Nr. 7550.

Milwaukee, USA, 6-February-2015
Milwaukee, USA, 6.Februar.2015



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- 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** 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** Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Essential Performance
6. **EN 60601-1-2:2007** Medical Electrical Equipment – Part 1-2: General Requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility - Requirements and tests
7. **EN 60601-1-4:1996/A1:1999** Medical Electrical Equipment - Part 1-4: General Requirements for Safety - Collateral standard: Programmable Electrical Medical Systems.
8. **EN 60601-1-6:2010** Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
9. **EN 60601-2-25:2011** Medical Electrical Equipment - Part 2-25: Particular requirements for basic safety and essential performance of electrocardiographs
10. **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
11. **EN 62304:2006** Medical device software - Software life-cycle processes
12. **EN 62366:2008** Medical devices - Application of usability engineering to medical devices
13. **EN 1041:2008** Information supplied by the manufacturer with medical devices
14. **EN 980:2008** Graphical symbols for use in the labeling of medical devices

This EC declaration of conformity supersedes the previous declaration dated 6-August-2014
Diese EG-Konformitätserklärung ersetzt die vorherige Erklärung mit Datum vom 6-August-2014

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ADDENDUM TO THE EC DECLARATION OF CONFORMITY dated 6-February-2015
ERGÄNZUNG ZUR KONFORMITÄTSERKLÄRUNG datiert 6.Februar.2015

Product Description Produktbezeichnung	Catalog Designation Katalogbezeichnung
ASSEMBLY - SPARSH	2056333-001
ASSY - SPARSH WITH KISS	2056333-002
<u>Unit Options</u>	
MAC 2000 UNIT	2063587-017
MAC 2000 KISS UNIT	2063587-018
MAC 2000 STRESS	2063587-140
<u>Accessory kit options</u>	
MAC 2000 STARTER KIT AHA ML DISPOSIBL8.5X11	2063587-075
MAC 2000 STARTERKIT AHA ML DISPOSABL A4	2063587-076
MAC 2000 STARTER KIT AHA ML UNIV LDS DISPOSABL/DED 8.5X11	2063587-077
MAC 2000 STARTER KIT AHA ML UNIV LDS DISPOSABL / DED A4	2063587-078
MAC 2000 STARTER KIT AHA VALUE REUSABL A4	2063587-079
MAC 2000 STARTER KIT IEC VALUE REUSABL A4	2063587-080
MAC 2000 STARTER KIT IEC ML PREMIUM REUSEABLE A4	2063587-081
MAC 2000 STARTER KIT IEC ML DISPOSABL A4	2063587-082
MAC 2000 STARTER KIT IEC ML UNIV LDS DISPOSABL A4	2063587-083
MAC 2000 STARTER KIT AHA ML PREMIUM REUSEABLE A4	2063587-156
Value Reusable Limb Clamps, IEC, 4/set	2029891-001
Value Reusable bulb electr 6/set boxed w/ label	2029892-001
Value Reusable Limb Clamps, AHA, 4/set	2029894-001
<u>Language Options</u>	
MAC 2000 ENG LANGUAGE NON-STRESS	2063587-019
MAC 2000 GER LANGUAGE NON-STRESS	2063587-020
MAC 2000 FRE LANGUAGE NON-STRESS	2063587-021
MAC 2000 SPA LANGUAGE NON-STRESS	2063587-022
MAC 2000 ITA LANGUAGE NON-STRESS	2063587-023
MAC 2000 JAP LANGUAGE NON-STRESS	2063587-024
MAC 2000 SWE LANGUAGE NON-STRESS	2063587-025
MAC 2000 DUT LANGUAGE NON-STRESS	2063587-026
MAC 2000 HUN LANGUAGE NON-STRESS	2063587-027
MAC 2000 RUS LANGUAGE NON-STRESS	2063587-028
MAC 2000 FIN LANGUAGE NON-STRESS	2063587-029
MAC 2000 CHI LANGUAGE NON-STRESS	2063587-030
MAC 2000 CZECH LANGUAGE NON-STRESS	2063587-031

Milwaukee, USA, 6-February-2015
Milwaukee, USA, 6.Februar.2015



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Product Description Produktbezeichnung	Catalog Designation Katalogbezeichnung
<u>Language Options (Continued)</u>	
MAC 2000 POL LANGUAGE NON-STRESS	2063587-032
MAC 2000 NOR LANGUAGE NON-STRESS	2063587-033
MAC 2000 SLO LANGUAGE NON-STRESS	2063587-034
MAC 2000 BRA POR LANGUAGE NON-STRESS	2063587-035
MAC 2000 DAN LANGUAGE NON-STRESS	2063587-036
MAC 2000 KOR LANGUAGE NON-STRESS	2063587-037
MAC 2000 EURO POR LANGUAGE NON-STRESS	2063587-038
MAC 2000 CRO LANGUAGE NON-STRESS	2063587-039
MAC 2000 GRE LANGUAGE NON-STRESS	2063587-040
MAC 2000 TUR LANGUAGE NON-STRESS	2063587-041
MAC 2000 EST LANGUAGE NON-STRESS	2063587-042
MAC 2000 LIT LANGUAGE NON-STRESS	2063587-043
MAC 2000 ROM LANGUAGE NON-STRESS	2063587-044
MAC 2000 BUL LANGUAGE NON-STRESS	2063587-045
MAC 2000 SER LANGUAGE NON-STRESS	2063587-046
MAC 2000 EGYPT LANGUAGE NON-STRESS	2063587-141
MAC 2000 VENEZUELA-SPA LANGUAGE NON-STRESS	2063587-142
MAC 2000 MEXICO-SPA LANGUAGE NON-STRESS	2063587-143
MAC 2000 INDONESIA LANGUAGE NON-STRESS	2063587-144
MAC 2000 ENG LANGUAGE W/STRESS	2063587-047
MAC 2000 GER LANGUAGE W/STRESS	2063587-048
MAC 2000 FRE LANGUAGE W/STRESS	2063587-049
MAC 2000 SPA LANGUAGE W/STRESS	2063587-050
MAC 2000 ITA LANGUAGE W/STRESS	2063587-051
MAC 2000 JAP LANGUAGE W/STRESS	2063587-052
MAC 2000 SWE LANGUAGE W/STRESS	2063587-053
MAC 2000 DUT LANGUAGE W/STRESS	2063587-054
MAC 2000 HUN LANGUAGE W/STRESS	2063587-055
MAC 2000 RUS LANGUAGE W/STRESS	2063587-056
MAC 2000 FIN LANGUAGE W/STRESS	2063587-057
MAC 2000 CHI LANGUAGE W/STRESS	2063587-058
MAC 2000 CZECH LANGUAGE W/STRESS	2063587-059
MAC 2000 POL LANGUAGE W/STRESS	2063587-060
MAC 2000 NOR LANGUAGE W/STRESS	2063587-061
MAC 2000 SLO LANGUAGE W/STRESS	2063587-062
MAC 2000 BRA POR LANGUAGE W/STRESS	2063587-063
MAC 2000 DAN LANGUAGE W/STRESS	2063587-064
MAC 2000 KOR LANGUAGE W/STRESS	2063587-065
MAC 2000 EURO POR LANGUAGE W/STRESS	2063587-066
MAC 2000 CRO LANGUAGE W/STRESS	2063587-067

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Milwaukee, USA, 6.Februar.2015



Douglas Keritz
Regulatory Affairs Director



Product Description Produktbezeichnung	Catalog Designation Katalogbezeichnung
<u>Language Options (Continued)</u>	
MAC 2000 GRE LANGUAGE W/STRESS	2063587-068
MAC 2000 TUR LANGUAGE W/STRESS	2063587-069
MAC 2000 EST LANGUAGE W/STRESS	2063587-070
MAC 2000 LIT LANGUAGE W/STRESS	2063587-071
MAC 2000 ROM LANGUAGE W/STRESS	2063587-072
MAC 2000 BUL LANGUAGE W/STRESS	2063587-073
MAC 2000 SER LANGUAGE W/STRESS	2063587-074
MAC 2000 EGYPT LANGUAGE W/STRESS	2063587-145
MAC 2000 VENEZUELA-SPA LANGUAGE W/STRESS	2063587-146
MAC 2000 MEXICO-SPA LANGUAGE W/STRESS	2063587-147
MAC 2000 INDONESIA LANGUAGE W/STRESS	2063587-148
<u>Power Cord Options</u>	
MAC 2000 N AMERICAN POWERCORD	2063587-085
MAC 2000 EURO POWERCORD	2063587-086
MAC 2000 BRITISH POWER CORD	2063587-087
MAC 2000 ITALIAN POWER CORD	2063587-088
MAC 2000 AUSTRALIAN POWER CORD	2063587-089
MAC 2000 ISRAELI POWER CORD	2063587-090
MAC 2000 SWISS POWER CORD	2063587-091
MAC 2000 INDIAN POWER CORD	2063587-092
MAC 2000 CHINESE POWER CORD	2063587-093
MAC 2000 JAPANESE POWER CORED	2063587-094
MAC 2000 BRAZIL POWER CORD	2063587-095
MAC 2000 EURO POWERCORD (EURO MFG)	2063587-149
<u>Analysis Options</u>	
MAC 2000 MEASUREMENT BY 12SL	2063587-096
MAC 2000 MEASUREMENT INTERPRETATION BY 12SL	2063587-097
MAC 2000 MEASUREMENT IINTERPRETATION ACITIPi BY 12SL	2063587-098
MAC 2000 MEASUREMENT BY HEART	2063587-099
MAC 2000 MEASUREMENT INTERP BY HEART	2063587-100
<u>Storage And Export Options</u>	
MAC 2000 INT STOR 100 - SDCD PDF/XML/HT	2063587-101
MAC 2000 INT STOR 200 - SDCD PDF/XML/HT	2063587-102
MAC 2000 INT STOR 100 - SDCD XML/HT	2063587-103
MAC 2000 INT STOR 200 - SDCD XML/HT	2063587-104

Milwaukee, USA, 6-February-2015
Milwaukee, USA, 6.Februar.2015



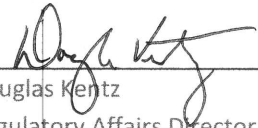
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Product Description Produktbezeichnung	Catalog Designation Katalogbezeichnung
<u>Workflow Executive Packages Options</u>	
MAC2000 ADT - MUSE LAN SERL CONN - INT STOR 200 - SDCD PDF/XML/HT	2063587-150
MAC2000 ADT SIMP ORDRS - MUSE LAN SERL CONN - INT STOR 200 -SDCD PDF/XML/HT	2063587-151
MAC2000 ADT ADV ORDRS - MUSE LAN SERL CONN - INT STOR 200 - SDCD PDF/XML/HT	2063587-152
MAC2000 CARDIOSOFT LAN SERL CONN - INT STOR 200 - SDCD PDF/XML/HT	2063587-153
MAC2000 PC LAN CONN - INT STOR 200 - SDCD PDF/XML/HT	2063587-154
MAC2000 MUSE LAN SERL CONN - INT STOR 200 - SDCD PDF/XML/HT	2063587-155
MAC2000 ADT - NON-MUSE LAN CONN - INT STOR 200 - SDCD PDF/XML/HT	2063587-157
MAC2000 ADT SIMP ORDRS - NON-MUSE LAN CONN - INT STOR 200-SDCD PDF/XML/HT	2063587-158
MAC2000 ADT ADV ORDRS - NON-MUSE LAN CONN - INT STOR 200 - SDCD PDF/XML/HT	2063587-159
<u>WIFI CHNL 11 /Modem Option</u>	
MAC 2000 WIFI CHANNEL 11 TO CARDIOSOFT	2063587-110
MAC 2000 WIFI CHANNEL 11 TO MUSE	2063587-111
<u>WIFI CHNL 13 /Modem Option</u>	
MAC 2000 MODEM	2063587-112
MAC 2000 WIFI CHANNEL 13 TO MUSE	2063587-113
MAC 2000 WIFI CHANNEL 13 TO CARDIOSOFT	2063587-114
<u>Pharma Options</u>	
MAC 2000 AUDIT TRAIL EXPORT	2063587-122
MAC 2000 CT DATA GUARD	2063587-123
<u>Barcode Options</u>	
MAC 2000 ENG BARCODE	2063587-124
MAC 2000 GER BARCODE	2063587-125
MAC 2000 FRE BARCODE	2063587-126
MAC 2000 SPA BARCODE	2063587-127
MAC 2000 ITA BARCODE	2063587-128
MAC 2000 SWE BARCODE	2063587-129
MAC 2000 DUT BARCODE	2063587-130
MAC 2000 HUN BARCODE	2063587-131
MAC 2000 RUS BARCODE	2063587-132
MAC 2000 FIN BARCODE	2063587-133
MAC 2000 CZE BARCODE	2063587-134
MAC 2000 NOR BARCODE	2063587-135
MAC 2000 SLO BARCODE	2063587-136
MAC 2000 POR BARCODE	2063587-137
MAC 2000 DAN BARCODE	2063587-138
<u>RR OPTION</u>	
MAC 2000 RR ANALYSIS	2063587-106

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