GE Healthcare

EC Declaration of Conformity

EG Konformitätserklärung

Document No. DOC 0787264

Manufacturer/ Hersteller:
GE Ultrasound Korea Ltd
65-1, Sangdaewon-dong
Jungwon-gu, Seongnam-si
Gyeonggi-do 462-120, Korea

Authorized EU Representative/ EU Repräsentant:
GE Medical Systems Information Technologies GmbH
Munzingerstrasse 5
79111 Freiburg, Germany

We herewith declare that the product/ *Wir erklären hiermit, dass das Produkt*

GE Diagnostic Ultrasound Imaging System,
(including system components and accessorie/*einschließlich Systemkomponenten und Zubehör)*
UMDNS-Code: 15-976; *GMDN-Code:* 40761

fulfills the requirements of the following directives, standards and normative documents:
mit den folgenden Richtlinien, Normen und normativen Dokumenten übereinstimmt:

1. Council Directive 93/42/EEC of 14 June 1993 concerning medical devices
2. EN 60601-1:1990 Medical electrical equipment - Part 1: General requirements for safety (IEC 60601-1:1988) with : Amendment A1:1993 to EN 60601-1:1990 (IEC 60601-1:1988/A1:1991) and Amendment A2:1995 to EN 60601-1:1990 (IEC 60601-1:1988/A2:1995), EN 60601-1:2006 Medical Electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005)
3. EN 60601-1-1:2001 Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems (IEC 60601-1-1:2000)
4. EN 60601-1-2:2001 Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests (IEC 60601-1-2:2001) with Amendment A1:2006 to EN 60601-1-2:2001 (IEC 60601-1-2:2001/A1:2004) AND EN 55011:1991 / CISPR 11:1990 modified, device group 1, class A, 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 (IEC 60601-1-2:2007)
5. EN 60601-2-37:2001 Medical electrical equipment - Part 2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment (IEC 60601-2-37:2001) with Amendment A1:2005 to EN 60601-2-37:2001(IEC 60601-2-37:2001/A1:2004) and Amendment A2:2005 to EN 60601-2-37:2001 (IEC 60601-2-37:2001/A2:2005), EN 60601-2-37:2008 Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment (IEC 60601-2-37:2007)
6. EN 60601-1-4:1996/A1:1999 Medical electrical eEquipment - Part 1-4- General requirements for safety- Collateral standard: Programable electrical medical systems (IEC 60601-1-4:1996/A1:1999)
7. EN 60601-1-6:2007 Medical electrical equipment – Part 1-6- General requirements for basic safety and essential performance- Collateral standard: Usability (IEC 60601-1-6:2006)

Compliance of the designated product with the Directive 93/42/EEC has been certified by:
Die Übereinstimmung des bezeichneten Produktes mit der Richtlinie 93/42/EWG wird bescheinigt durch:

GE Ultrasound Korea Ltd.
Technical Dossier DOC0787261

The medical device has been assigned to class **IIa** as specified in the Directive 93/42/EEC. It bears the mark
Das Medizinprodukt ist eingestuft in die Klasse **IIa** *gemäss der Richtlinie 93/42/EWG, es trägt die Kennzeichnung*

GE Healthcare

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The designated product has been designed and manufactured under a quality management system according to EN ISO 13485: 2003 and Annex II of Directive 93/42/EEC concerning medical devices.
The conformity of the quality management system has been certified by:
Das bezeichnete Produkt wurde unter Anwendung des Qualitätsmanagementsystems gemäss ISO 13485:2003 und Anhang II der Richtlinie 93/42/EWG über Medizinprodukte entwickelt, hergestellt und geprüft. Die Konformität des Qualitätsmanagementsystems wird bescheinigt durch:

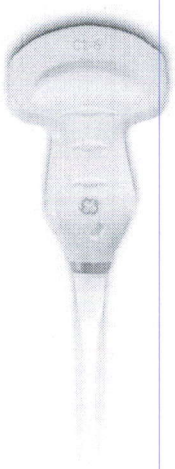
LNE/G-MED France

Seongnam /Korea , Oct. 4th. 2010

Kim, Hyeonho Kim – RA Leader

The technical documentation is filed at/ Die technische Doukmentation ist archiviert bei
GE Ultrasound Korea

GE C1-6-D XDCLEAR CURVED ARRAY PROBE (CONVEX)



The GE C1-6-D XDclear Curved Array Probe (Convex) is designed for reliability and durability. By following recommended care and handling procedures, you can help maximize your transducer's performance and product life.

GE Authorized Dealer

SKU: H40472LT

Category: Transducers

ADDITIONAL INFORMATION REVIEWS (0) FAQ

MORE	
BRAND	GE Healthcare
AVAILABILITY	New
MACHINE COMPATIBILITY	GE LOGIQ E9 XDclear 2.0 GE LOGIQ S7 with XDclear GE LOGIQ S8 XDclear 2.0 GE Vivid E90 GE Vivid E95 GE Vivid S60 GE Vivid S70
PROBE TYPE	Convex
FREQUENCY RANGE	1.0 - 6.0 MHz
APPLICATION	Abdominal Gynecology Obstetrics
FIELD OF VIEW	80