PHILIPS

CE 0123 **DECLARATION OF CONFORMITY**

Declares under our sole responsibility that the product:

Product Name:	**Magnetic Resonance Equipment**
Product Model Number or Designator:	**Multiva 1.5T**
Date of issue:	**2012-10-11**
Device Classification:	**Class IIa, Rule 10 according to ANNEX IX to Directive 93/42/EEC**
Global Medical Device Nomenclature Code (GMDN):	**41162**
Product Options/Accessories:	**Listed in product accompanying documentation**

To which this declaration relates is in conformity with the provisions of Council Directive: 93/42/EEC (Medical Devices Directive) amended by 2007/47/EC.

The Manufacturer is certified by the Notified Body listed below to EN ISO 13485 and Annex II excluding section 4 of the Medical Device Directive 93/42/EEC amended by 2007/47/EC. Copies of the Quality System certificates are available upon request.

Manufacturer:	**Philips Healthcare (Suzhou) Co., Ltd.** **258 Zhongyuan Road, Suzhou Industrial Park,** **Jiangsu Province, P.R.C 215024**
Authorised Representative:	**Philips Medical Systems Nederland B.V.** **Quality & Regulatory Affairs** **Veenpluis 4-6, 5684PC Best, The Netherlands**
Notified Body:	**TÜV SÜD Product Service GmbH** **Ridlerstr.65, 80339, München, Germany**
Supplementary Information:	**N/A**

The products listed above have been tested in a typical configuration as described in the Manufacturer's accompanying documentation, and are fully compliant with the standards listed on next page. Additionally the products listed above have been designed, manufactured, tested, and found to be compatible with the devices and accessories described by the manufacturer in the devices accompanying documentation.

Signed for and on behalf of Philips Healthcare (Suzhou) Co., Ltd.

Place of Issue: Suzhou, China

Date: 2012-10-11

Jian Shu
Regulatory Manager
Philips Healthcare (Suzhou) Co., Ltd.

Soctt Zhang
Director of Quality & Regulatory
Philips Healthcare (Suzhou) Co., Ltd.

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Concerned Standards

Product(s): **Multiva 1.5T**

We confirm, that the safety and effectiveness have been achieved in the design and manufacture of the equipment mentioned above according to the requirements of the following harmonised standards. The equipment will be safe and effective when used in accordance with the instructions by suitably qualified personnel.

The standards, as applicable to the above product(s), are:

EN 60601-1: 1990 + A1: 1993 + A2: 1995	Medical electrical equipment. Part 1: General requirements for safety.
EN 60601-1-1: 2001	Medical electrical equipment -- Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems.
EN 60601-1-2:2001 + A1:2006	Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests.
EN 60601-1-4: 1996 + A1: 1999	Medical electrical equipment – Part 1-4: General requirements for safety – Collateral standard: Programmable Electrical Medical Systems
EN 60601-1-6:2004	Medical electrical equipment -- Part 1-6: General requirements for safety - Collateral standard: Usability
EN 60601-2-33:2002 + A1: 2005 + A2: 2008	Medical electrical equipment – Part 2-33: Particular requirements for the safety of magnetic resonance equipment for medical diagnosis.
EN ISO 10993-1:2009	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process