CE 0197

DECLARATION OF CONFORMITY

Philips Medical Systems (Cleveland), Inc.
Business Unit CT
595 Miner Rd.
Cleveland, OH 44143 USA

Declares under our sole responsibility that the product:

Product:	Full Body CT System	Technical File:	DHF172557
Model/Configuration:	Ingenuity Flex	MDD Classification:	IIb
Model/Catalog Number	728317	Rule Number:	Annex IX, Rule 10
Options/Accessories	DHF167085	GMDN Code:	37618

To which this Declaration relates is in conformity with the provisions of Council Directive: 93/42/EEC (Medical Devices Directive). This statement of conformity is valid in connection with the release document for the respective batch of produced devices.

The aforementioned products have been evaluated and tested in a typical configuration as described in the Manufacturers accompanying documentation, and are found to comply with the following standards as required by the EC Directive 93/42/EEC (MDD), as amended, to demonstrate conformance to MDD Annex I Essential Requirements:

STANDARD NO.	STANDARD TITLE
EN ISO 13485:2012	Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes
EN 980:2008	Graphical Symbols for the Use in The Labeling of Medical Devices
EN 1041:2008	Information supplied by the manufacturer with medical devices
EN ISO 14971:2012	Medical Devices — Application of risk management to medical devices
EN 60601-1:1990 /AI:1 993/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 /AI:2006	Medical electrical equipment- Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests
EN 60601-1-3:1994	Medical electrical equipment- Part 1-3: General requirements for safety. Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment
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 60601-2-28:1993	Medical Electrical Equipment - Part 2: Particular Requirements for the Safety of X-Ray Source Assemblies and X-Ray Tube Assemblies for Medical Diagnosis
EN 60601-2-32:1994	Medical electrical equipment- Part 2: Particular requirements for the safety of associated equipment of X-ray equipment
EN 60601-2-44:2001 /A1:2003	Medical electrical equipment- Part 2-44: Particular requirements for the safety of X-ray equipment for computed tomography

The Manufacturer is certified by the Notified Body listed below to EN ISO 13485 (QMS certificate #SX 60028376 0001 expiring 13- Nov-2014) and Annex II-Section 3.2 (EC Certificate No. #HD 60028376 0001 expiring 13-Nov-2014) (with the exception of point 4 per Article 11), of the Medical Device Directive 93/42/EEC.

Mel L Novatny

Melinda Novatny
Sr. Manager, Regulatory Affairs

27 Jan 2013

Date Issued
Cleveland, Ohio, USA

European Representative:
Philips Medical Systems Nederland B.V.
Quality & Regulatory Affairs
Veenpluis 4-6
5684 PC Best
The NETHERLANDS

Notified Body
TÜV Rheinland LGA Products GmbH
Tillystraße 2
90431 Nürnberg
Germany
Notified Body number: 0197