

PHILIPS

DECLARATION OF CONFORMITY

Philips Healthcare (Suzhou) Co., Ltd.

**No. 258, ZhongYuan Road, Suzhou Industrial Park, 215024
Suzhou, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA**

**This declaration of conformity is issued under the sole responsibility of the manufacturer.
The device covered by the present declaration is in conformity with all regulations below
and other relevant Union legislation**

Product Name:	Full-body CT System	
Intended Purpose:	Computed Tomography X-Ray System is intended to produce images of the head and body by computer reconstruction of x-ray transmission data taken at different angles and planes. This device includes Data acquisition system, detection management system and an operating console with display monitors along with patient and system supporting devices, accessories and components.	
Product Designator/Product Part Number(s):	Incisive CT (728144)	
Basic UDI-DI	0884838BM285T6	
Control Indicator:	Effective on 19-Aug-2021, detailed S/N's as controlled in production system	
Medical Device Nomenclature Code and Description	GMDN Title	Full-body CT System
	GMDN Code:	37618
	GMDN Description:	An assembly of diagnostic x-ray computed tomography (CT) devices with a gantry large enough to allow imaging of any part of the body. It includes designs with single or multiple fixed annular arrays of x-ray tubes and opposing detectors or those with x-ray tube(s) and opposing detector assemblies that rotate rapidly around a central axis point within the gantry imaging area. It can produce two and/or three-dimensional (3-D) cross-sectional (tomographic) images, including spiral CT or other special imaging applications at multiple specified angles in relation to body position. It may use a variety of digital techniques for information capture, image reconstruction, and display.
	CND Code:	Z110306
	CND Title:	COMPUTED TOMOGRAPHY SCANNING SYSTEMS (CT)
EU Authorized Representative:	Philips Medical Systems Nederland B.V. Veenpluis 6, 5684 PC Best, The Netherlands	
Quality Certificates Issued:	ISO 13485 Certified No. Q5 080330 0034;	

	EU Quality Management System Certificate (MDR) No. G10 080330 0050
Product Options/Accessories:	N/A

The object of the declaration described above is in conformity with the following regulations:

EU Regulation	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.	
Device Risk Classification	Class IIb based on Annex VIII and rule 10 and 11.	
Conformity Assessment Path	Annex IX	
Name/Address/ID of Notified Body	TÜV SÜD Product Service GmbH Ridlerstraße 65, 80339 München, Germany Notified Body identification no. 0123	
Standards and Common Specifications	The products listed above have been tested in a typical configuration as described in the Manufacturer's accompanying documentation, and are compliant with the product standards listed below	
	EN 60601-1: 2006 /A1:2013	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
	EN 60601-1-2:2015	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
	EN 60601-1-3:2008 /A11:2016	Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment
	EN 60601-1-6:2010 /A1:2015	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
	EN 60601-2-44:2016	Medical electrical equipment - Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography
	EN 62366-1: 2015	Medical devices - Application of usability engineering to medical device
	EN 62304:2006 /A1:2015	Medical device software - Software life-cycle process
	EN ISO 14971:2012	Medical devices - Application of risk management to medical devices

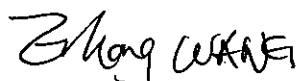
	EN 1041:2008/A1:2013	Information supplied by the manufacturer of medical devices
	EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2016, Corrected version 2017-03)
	EN ISO 10993-1:2009 /AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
Relevant Legislation	The products above are compliant to the following relevant regulations and directives • Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, • Directive (EU) 2015/863 of 31 March 2015 amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances • Radio Equipment Directive 2014/53/EU.	

Supplementary Information:

Note that the Notified Body number does not apply to the 2011/65/EU (restriction of the use of certain hazardous substances in electrical and electronic equipment) Directive, Directive (EU) 2015/863 of 31 March 2015 amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances and Radio Equipment Directive 2014/53/EU.

Signature (signed for and on behalf of Philips):

Date of Issue:



19-Aug-2021

Printed Name: Erhong Wang

Place of Issue: Suzhou, China

Title: Senior Regulatory Manager (PRfRC)

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