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 (728143)
Basic UDI-DI	0884838BM285T6
Control Indicator:	Effective on 01-Aug-2020, 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; • 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 and Radio Equipment Directive 2014/53/EU.

Signature (signed for and on behalf of Philips): Date of Issue:

Erhong WANG 31-Jul-2020

Printed Name: Erhong Wang Place of Issue: Suzhou, China

Title: Senior Regulatory Manager (PRfRC) DEP158938

Benannt durch Designated by Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten www.zlg.de
BS-MDR-099

Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 080330 0050 Rev. 00

Manufacturer:

Philips Healthcare (Suzhou) Co., Ltd.
No. 258, ZhongYuan Road
Suzhou Industrial Park
215024 Suzhou, Jiangsu Province
PEOPLE'S REPUBLIC OF CHINA

Authorized Representative:

Philips Medical Systems Nederland B.V.
Veenpluis 6, 5684 PC Best, THE NETHERLANDS

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.

Report No.: SH1963203

Valid from: 2020-05-28
Valid until: 2025-05-27

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2020-05-28

SOCIETATEA COMERCIALĂ, REPUBLICA MOLDOVA S.R.L. "REPROMED" IDNO 1005600054971

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BS-MDR-099

Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class IIa and Class IIb Devices)

No. G10 080330 0050 Rev. 00

Device Group:	Z110306 - COMPUTED TOMOGRAPHY SCANNING SYSTEMS (CT)
Classification:	IIb
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.

Device Group:	Z110501 - MAGNETIC RESONANCE IMAGING SYSTEMS
Classification:	IIb
Intended Purpose:	Philips Magnetic Resonance (MR) systems are Medical Electrical Systems indicated for use as a diagnostic device. This MR system enables trained physicians to obtain cross-sectional images, spectroscopic images and/or spectra of the internal structure of the head, body or extremities, in any orientation, representing the spatial distribution of protons or other nuclei with spin. Image appearance is determined by many different physical properties of the tissue and the anatomy, the MR scan technique applied, and presence of contrast agents. The use of contrast agents for diagnostic imaging applications should be performed consistent with the approved labeling for the contrast agent. The trained clinical user can adjust the MR scan parameters to customize image appearance, accelerate image acquisition, and synchronize with the patient's breathing or cardiac cycle. The systems can use combinations of images to produce physical parameters, and related derived images. Images, spectra, and measurements of physical parameters, when interpreted by a trained physician, provide information that may assist diagnosis and therapy planning. The accuracy of determined physical parameters depends on system and scan parameters and must be controlled and validated by the clinical user. In addition the Philips MR systems provide imaging capabilities, such as MR fluoroscopy, to guide and evaluate interventional and minimally invasive procedures in the head, body and extremities. MR Interventional procedures, performed inside or adjacent to the Philips MR system, must be performed with MR Conditional or MR Safe instrumentation as selected and evaluated by the clinical user for use with the specific MR system configuration in the hospital. The appropriateness and use of information from a Philips MR system for a specific interventional procedure and specific MR system configuration must be validated by the clinical user.

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No. G10 080330 0050 Rev. 00

Device Group:	Z110311 - DIRECT DIGITAL X-RAY SYSTEMS
Classification:	IIb
Intended Purpose:	The X-Ray system is intended for use in generating radiographic images of human anatomy by qualified/trained doctor or technician. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position. This device is not intended for mammographic applications. All standard radiography procedures (DR) must be possible: • X-ray examinations of the skeleton including upper extremities, lower extremities, spine, pelvis, skull, ribs, etc. (eg. Elbow Lat, Shoulder Axial etc.) • X-ray examinations of the thorax. (e.g. chest PA etc.) • X-ray of soft tissues (e.g. abdomen) but excluding mammography. Special examinations like Tomography do not belong to this X-Ray system. This is not the main focus of examination workflow.
Device Group:	Z110501 - MAGNETIC RESONANCE IMAGING SYSTEMS
Classification:	IIa
Intended Purpose:	/
The validity of this certificate depends on conditions and/or is limited to the following:	-none-

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