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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



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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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(Class IIa and Class IIb Devices)

No. G10 080330 0050 Rev. 00

Device Group:

Z110311 - DIRECT DIGITAL X-RAY SYSTEMS

Classification:

11b

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:

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The validity of this certificate depends on conditions and/or is limited to the following: