ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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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 011876 0030 Rev. 01

Manufacturer:

Philips Medical Systems DMC GmbH
Röntgenstraße 24
22335 Hamburg
GERMANY

SRN Manufacturer - DE-MF-000005362

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. All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G10 011876 0030 Rev. 01

Report No.:	713351680
Preceding Certificate No.:	G10 011876 0030 Rev. 00
Valid from:	2025-05-28
Valid until:	2030-05-27
Date of Initial Issuance:	2020-05-28

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2025-03-18

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Classification:	Class IIb
Device Group:	Z11039009 - FLUOROSCOPY DEVICES
Intended Purpose:	The CombiDiagnost R90 is a multi-functional general R/F system. It is suitable for all routine radiography and fluoroscopy exams, including specialist areas like angiography or pediatric work, excluding mammography

Classification:	Class IIb
Device Group:	Z11039016 - MOBILE RADIOGRAPHIC UNITS
Intended Purpose:	Radiography 7000 M is intended for use by adequately trained, qualified, and authorized healthcare professionals on both adult and pediatric patients who cannot be transferred to the stationary X-ray system for taking diagnostic radiographic exposures for the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in prone or supine positions

Classification:	Class IIb
Device Group:	Z11039011 - HIGH VOLTAGE X-RAY GENERATORS
Intended Purpose:	The X-ray High Voltage generator is intended to supply high voltage to the X-ray tube housing assembly to initiate emission of X-ray radiation by the X-ray tube that enables the creation of diagnostic images of human patients. The X-ray High Voltage Generator is only used as integrated part of an imaging system and has no medical purpose by its own. The intended treatment, duration and treatment parameters are not defined on X-ray High Voltage Generator assembly level. This is defined by the manufacturer of the imaging system in accordance with the intended use, the intended purpose and the medical purpose as described in the technical documentation of the imaging system

Classification:	Class IIb
Device Group:	Z11039012 - X-RAY TUBE ASSEMBLY
Intended Purpose:	The X-ray tube housing assembly is an X-ray generating tube encased in a radiation-shielded housing. The X-ray tube housing assembly is intended to emit X-ray photons to enable the creation of diagnostic images of human patients. The X-ray tube housing assembly is only used as integrated part of an imaging system and has no medical purpose by its own. The intended treatment, duration and treatment parameters are not defined on X-ray tube housing assembly level. This is defined by the manufacturer of the imaging system in accordance with the intended use, the intended purpose and the medical purpose as described in the technical documentation of the imaging system

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Classification:	Class IIb
Device Group:	Z11039080 - VARIOUS RADIODIAGNOSTIC AND INTERVENTIONAL INSTRUMENTS - HARDWARE ACCESSORIES
Intended Purpose:	Stationary x-ray grid
Classification:	Class IIb
Device Group:	Z110390 - VARIOUS INSTRUMENTS FOR RADIODIAGNOSTICS AND INTERVENTIONAL PROCEDURES
Intended Purpose:	The DigitalDiagnost C90 is intended to acquire, process, store, display and export digital radiographic images. The DigitalDiagnost C90 is suitable for all routine radiography examinations, including specialist areas like intensive care, trauma or pediatric work, excluding fluoroscopy, angiography and mammography
Classification:	Class IIb
Device Group:	Z11039009 - FLUOROSCOPY DEVICES
Intended Purpose:	ProxiDiagnost N90 is a multi-functional general R/F system. It is suitable for all routine radiography and fluoroscopy exams, including specialist areas like angiography or pediatric work, excluding mammography.
Classification:	Class IIb
Device Group:	Z110390 - VARIOUS INSTRUMENTS FOR RADIODIAGNOSTICS AND INTERVENTIONAL PROCEDURES
Intended Purpose:	The DigitalDiagnost 4.3 is intended to acquire, process, store, display and export digital radiographic images. The DigitalDiagnost 4.3 is suitable for all routine radiography examinations, including specialist areas like intensive care, trauma or pediatric work, excluding fluoroscopy, angiography and mammography.
Classification:	Class IIb
Device Group:	Z110390 - VARIOUS INSTRUMENTS FOR RADIODIAGNOSTICS AND INTERVENTIONAL PROCEDURES
Intended Purpose:	The Radiography 7300 C is intended to acquire, process, store, display and export digital radiographic images. The Radiography 7300 C is suitable for all routine radiography examinations, including specialist areas like intensive care, trauma or pediatric work, excluding fluoroscopy, angiography and mammography.
The validity of this certificate depends on conditions and/or is limited to the following:	-

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Revision History:

Rev.	Dated	Report	Description
00	2020-05-28	713170831	-
01	2025-05-28	713351680	Renewal of certificate

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