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

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 098883 0006 Rev. 01

Manufacturer:

Neusoft Medical Systems Co., Ltd.
No. 177-1 Chuangxin Road
Hunnan District
110167 Shenyang, Liaoning
PEOPLE'S REPUBLIC OF CHINA

SRN Manufacturer - CN-MF-000011819

Authorized Representative:

Emergo Europe B.V.
Westervoortsedijk 60, 6827 AT Arnhem, 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.
All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G10 098883 0006 Rev. 01

Report No.: BJ23010302

Preceding Certificate No.: G10 098883 0006 Rev. 00

Valid from: 2024-03-14
Valid until: 2026-10-18
Date of Initial Issuance: 2021-10-19

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2024-03-14

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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Classification:	Class IIb
Device Group:	Z110306 - COMPUTED TOMOGRAPHS (CT)
Intended Purpose:	Multi-Slice CT Scanner System can be used as a whole body computed tomography X-ray system featuring a continuously rotating X-ray tube and detector array. The acquired X-RAY transmission data is reconstructed by computer into cross-sectional images of the body from either the same axial plane taken at different angles or spiral planes taken at different angles.
Classification:	Class IIb
Device Group:	Z110301 - DIGITAL ANGIOGRAPHY SYSTEMS
Intended Purpose:	Medical X-ray Angiography System is indicated for use in generating fluoroscopy, radiography and digital subtraction angiography X-ray images of human anatomy during vascular and non-vascular angiography examination and interventional procedures.
The validity of this certificate depends on conditions and/or is limited to the following:	-none-

Revision History:

Rev.	Dated	Report	Description
00	2021-10-19	BJ20010307	-
01	2024-03-14	BJ23010302	Amended: Change of authorized representative's data

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