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. 02

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, 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 098883 0006 Rev. 02

Report No.: BJ22010301

Preceding Certificate No.: G10 098883 0006 Rev. 01

Valid from: 2024-12-05
Valid until: 2026-10-18

Date of Initial Issuance: 2021-10-19

Issue date: 2024-12-05

Christoph Dicks
Head of Certification/Notified Body

Digitally signed by Bolea Petru
Date: 2025.05.23 14:39:17 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

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TÜV SÜD Product Service

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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. 02

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.

Classification:	Class IIb
Device Group:	Z110311 - DIRECT DIGITAL RADIOLOGY (DR) SYSTEMS
Intended Purpose:	Digital Radiography System is suitable for digital X-ray radiography examinations. For the chest, abdomen, bone and soft tissue in different parts of photography, obtaining the images for clinical diagnosis.

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
02	2024-12-05	BJ22010301	Supplemented: Device(s)/group of device(s) added

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中华人民共和国
PEOPLE' S REPUBLIC OF CHINA
医疗器械产品出口销售证明
CERTIFICATE FOR EXPORTATION OF MEDICAL PRODUCTS

证书编号：辽沈药监械出 20250003 号
Certificate NO.: liaoshenyaojianxiechu20250003

产品名称:X 射线计算机体层摄影设备
Product(s):Multi-slice CT Scanner System

规格型号：NeuViz 64 In-Mobile; NeuViz 64 In; NeuViz Glory; NeuViz Epoch; NeuViz ACE、NeuViz ACE SP; NeuViz 128; NeuViz 128 Plus; NeuViz Prime; NeuViz 16 Classic; NeuViz ACE 64e; NeuViz Glory+; NeuViz ACE UP; NeuViz ACE 64i; NeuViz Epoch+; NeuViz ACE 32; NeuViz ACE 32e; NeuViz ACE 128
Model: NeuViz 64 In-Mobile; NeuViz 64 In; NeuViz Glory; NeuViz Epoch; NeuViz ACE、NeuViz ACE SP; NeuViz 128; NeuViz 128 Plus; NeuViz Prime; NeuViz 16 Classic; NeuViz ACE 64e; NeuViz Glory+; NeuViz ACE UP; NeuViz ACE 64i; NeuViz Epoch+; NeuViz ACE 32; NeuViz ACE 32e; NeuViz ACE 128

产品注册或备案凭证号：国械注准 20223060465；国械注准 20193061954；国械注准 20193060179；国械注准 20203060462；国械注准 20203060680；国械注准 20153061278；国械注准 20203060578；国械注准 20183060065；国械注准 20143061978；国械注准 20233060911；国械注准 20233060914；国械注准 20233061059；国械注准 20233061169；国械注准 20233061364；国械注准 20233061733；国械注准 20243060444；国械注准 20243060168
Registration certificate(s): guoxiezhuzhun20223060465; guoxiezhuzhun20193061954; guoxiezhuzhun20193060179; guoxiezhuzhun20203060462; guoxiezhuzhun20203060680; guoxiezhuzhun20153061278; guoxiezhuzhun20203060578; guoxiezhuzhun20183060065; guoxiezhuzhun20143061978; guoxiezhuzhun20233060911; guoxiezhuzhun20233060914; guoxiezhuzhun20233061059; guoxiezhuzhun20233061169; guoxiezhuzhun20233061364; guoxiezhuzhun20233061733; guoxiezhuzhun20243060444; guoxiezhuzhun20243060168

生产企业：东软医疗系统股份有限公司
Manufacturer: Neusoft Medical Systems Co.,Ltd.

生产企业住所：辽宁省沈阳市浑南区创新路 177-1 号

Address of manufacturer: No. 177-1 Chuangxin Road, Hunnan District, Shenyang, Liaoning, China 110167

生产许可或备案凭证号：辽药监械生产许 20150053 号
Manufacturing License(s): liaoyaojianxieshengchanxu20150053

兹证明上述产品已准许在中国生产和销售。
This is to certify that the above products have been registered to be manufactured and sold in China.

证明有效日期至：2027 年 1 月 22 日
This certification valid until: 2027-01-22

备注：无
Remark: No

辽宁省药品监督管理局

2025 年 1 月 23 日

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Report No.: BJ22010301

Preceding Certificate No.: G10 098883 0006 Rev. 01

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Valid until: 2026-10-18

Date of Initial Issuance: 2021-10-19

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2024-12-05

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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. 02

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.

Classification:	Class IIb
Device Group:	Z110311 - DIRECT DIGITAL RADIOLOGY (DR) SYSTEMS
Intended Purpose:	Digital Radiography System is suitable for digital X-ray radiography examinations. For the chest, abdomen, bone and soft tissue in different parts of photography, obtaining the images for clinical diagnosis.

The validity of this certificate depends on conditions and/or is limited to the following:	-none-

Revision History:

Rev.	Dated	Report	Description
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01	2024-03-14	BJ23010302	Amended: Change of authorized representative's data
02	2024-12-05	BJ22010301	Supplemented: Device(s)/group of device(s) added

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Registration No. 04724Q10233R3L

CERTIFICATE
OF QUALITY MANAGEMENT SYSTEM

This is to certify that:

Neusoft Medical Systems Co., Ltd.

Registered address: **No. 177-1 Chuangxin Road, Hunnan District, Shenyang, Liaoning, China**

Manufacturing address: **No. 177-4 Chuangxin Road, Hunnan District, Shenyang, Liaoning, China; No. 177-7 Chuangxin Road, Hunnan District, Shenyang, Liaoning, China**

Operates a Quality Management System which complies with the requirements of:

GB/T 19001-2016 idt ISO 9001:2015

For the following scope:

The Design, Development, Production and Service of Diagnostic Ultrasound System, Diagnostic Ultrasound Equipment, Color Doppler Diagnostic Ultrasound System, Picture Archiving and Communication Systems, Advanced Visualization Workspace, MammoCAD, TeleCARE, NeuMiva Cloud, Portable Digital Radiography System, AVW.CT, AVW.MR, AVW.XRay, Vehicle-mounted Digital Radiography System, NeuBrainCARE, NeuMica EF, Advanced Visualization Workspace(AVW.Intelli.Coronary), NeuLungCARE-QA, High Voltage Generator Component(for Medical Device).

The Design, Development, Production, Installation and Service of Magnetic Resonance Imaging System, Medical Magnetic Resonance Imaging System, Computed Tomography Scanner System, Digital Mammography System, Digital X-Ray Radiography System, Digital Mobile Radiography System, Digital Angiographic System.

Date of issue: **June 22, 2024**

Date of expiry: **June 21, 2027**

General manager:

BEIJING HUA GUANG CERTIFICATION OF MEDICAL DEVICES CO., LTD.

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT IAF

CNAS

中国认可
国际互认
管理体系
MANAGEMENT SYSTEM
CNAS C047-M

Note: This certificate will not be continuously valid until the organization has been approved in the annual surveillance audit. The certificate information is available on the website of the certification and accreditation administration of the People's Republic of China (http://www.cnca.gov.cn) or the website of CMD (http://www.cmdc.com.cn). Address: 5th floor of Zhong Lian building, No.jia88, An Ding Men Wai street, Dongcheng district, Beijing,100011, P.R. China Telephone: 010-62351993

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

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 098883 0004 Rev. 03

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

Certification Mark:

TÜV SÜD EN ISO 13485 tuvsud.com/ps-cert

Scope of Certificate: **Design and Development, Production, Distribution and Service of Computed Tomography Scanner Systems, X-ray Imaging Systems, Magnetic Resonance Imaging Systems, Positron Emission Tomography(PET) and Computed Tomography(CT) Systems, Diagnostic Ultrasound Systems, Diagnostic X-ray High Voltage Generators, Picture Archiving and Communication Systems.**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). 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:Q5 098883 0004 Rev. 03

Report No.: BJ23010301

Valid from: 2023-07-10
Valid until: 2026-07-09

Date, 2023-07-05

Christoph Dicks
Head of Certification/Notified Body

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DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 098883 0004 Rev. 03

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

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

Design and Development, Production, Distribution and Service of Computed Tomography Scanner Systems, X-ray Imaging Systems, Magnetic Resonance Imaging Systems, Positron Emission Tomography(PET) and Computed Tomography(CT) Systems, Diagnostic Ultrasound Systems, Diagnostic X-ray High Voltage Generators, Picture Archiving and Communication Systems.

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