



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
www.zlg.de  
ZLG-BS-244.10.08



Product Service

# EC Certificate

Full Quality Assurance System  
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)  
(Devices in Class IIa, IIb or III)

**No. G1 098883 0002 Rev. 02**

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

**Product Category(ies):** **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 declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

**Report No.:** BJ1910307

**Valid from:** 2019-09-03

**Valid until:** 2024-05-26

**Date,** 2019-09-03

Stefan Preiß  
Head of Certification/Notified Body

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

A4 / 07-17



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## Facility(ies):

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

Neusoft Medical Systems Co., Ltd.  
 No.16 Shiji Road, Hunnan Industrial Area, 110179 Shenyang,  
 Liaoning, PEOPLE'S REPUBLIC OF CHINA

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