EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60083380 0001

Report No.: 15036681 005

Manufacturer:

Neusoft Medical Systems Co., Ltd.
No. 16, Shiji Road
Hunnan Industrial Area
Shenyang, Liaoning 110179
Liaoning
China

Products: Computed Tomography Scanner Systems, X-Ray Imaging Systems

Replaces Approval, Registration No.: HD 60075599 0001

Expiry Date: 2015-07-08

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2013-07-10

Date: 2013-07-10

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Dipl.-Ing. D. Meier

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

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Neusoft

EC Declaration of Conformity

Manufacturer:

Neusoft Medical Systems Co., LTD.
Address: No.16, Shiji Road,
Hunnan Industrial Area,
Shenyang, Liaoning, China, 110179

whose single Authorized Representative:

Emergo Europe
Address: Molenstraat 15, 2513 BH The Hague, The Netherlands

We, the manufacturer, herewith declare that the products

NeuViz 128

GMDN-Code: **37618**

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class IIb according to Annex IX of the Directive 93/42/EEC. It bears the mark

CE 0197

The product concerned has been designed and manufactured under a quality management system according to Annex II without Section 4 of Directive 93/42/EEC.

Compliance of the designated product with the Directive 93/42/EEC has been assessed and certified by the Notified Body

TÜV Rheinland LGA Products GmbH
Tillystraße 2, 90431, Nürnberg, Germany
Certificate *No.: HD 60083380 0001*
Issue date: 2013-07-10
Expiry date: 2015-07-08

following the procedure relating to the EC Declaration of Conformity set out in Annex II without Section 4 of Directive 93/42/EEC.

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

The above mentioned declaration of conformity is exclusively under the responsibility of

Company: ***Neusoft Medical Systems Co., LTD.***
Address: ***No.16, Shiji Road, Hunnan Industrial Area, Shenyang, Liaoning, China, 110179***

Genmiao Jiang
General Manager

Bin Zhao
TQM Director

Issued: 2015-4-13