

EC Declaration of Conformity

Manufacturer:

whose single Authorized Representative:

Neusoft Medical Systems Co., LTD.
Address: No. 177-1 Chuangxin Road,
Hunnan District, Shenyang,
Liaoning, China 110167

Emergo Europe
Address: Prinsessegracht 20, 2514 AP
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



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 SÜD Product Service GmbH
Ridlerstr 65, D-80339 München, Germany
Certificate No.: G1 098883 0002 Rev. 02
Issue date: 2019-09-03
Expiry date: 2024-05-26

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. 177-1 Chuangxin Road, Hunnan District,
Shenyang, Liaoning, China, 110167

Wu Shaojie
CEO

Wang Zhiqiang
TQM Director

Issued: 2019-09-19

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Address: Prinsessegracht 20, 2514 AP
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We, the manufacturer, herewith declare that the products
NeuViz Prime

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



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We, the manufacturer, herewith declare that the products
NeuViz Glory

GMDN-Code: 37618

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

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Emergo Europe
Address: Prinsessegracht 20, 2514 AP
The Hague, The Netherlands

We, the manufacturer, herewith declare that the products
NeuViz 64 In

GMDN-Code: 37618

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

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The Hague, The Netherlands

We, the manufacturer, herewith declare that the products
NeuViz 16 Essence

GMDN-Code: 37618

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

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Wu Shaojie
CEO

Wang Zhiqiang
TQM Director

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Emergo Europe
Address: Prinsessegracht 20, 2514 AP
The Hague, The Netherlands

We, the manufacturer, herewith declare that the products
NeuViz 16 Classic

GMDN-Code: 37618

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

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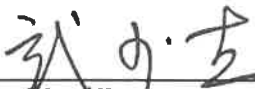
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Wu Shaojie
CEO



Wang Zhiqiang
TQM Director

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Emergo Europe
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The Hague, The Netherlands

We, the manufacturer, herewith declare that the products
NSM-S15P

UMDNS-Code: 16260

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

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



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Wu Shaojie
CEO

Wang Zhiqiang
TQM Director

Issued: September 18, 2019

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Emergo Europe
Address: Prinsessegracht 20, 2514 AP
The Hague, The Netherlands

We, the manufacturer, herewith declare that the products
NeuCare Mammo DR HD

GMDN-Code: 37672

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



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