

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 Zhigiang **TQM Director**

Issued: 2019-09-19

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Secrecy: Restrict



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 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

(€ 0123

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

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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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Secrecy: Restrict



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 Glorv

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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Wu Shaoiie **CEO**

Issued: 2019-9-19

Wang Zhiqiang **TQM Director**

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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 64 In

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

(€ 0123

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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

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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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Secrecy: Restrict



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 16 Essence

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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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

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Shenyang, Liaoning, China, 110167

Wu Shaoiie

CEO

Wang Zhigiang **TQM Director**

Issued: 2019-09-19

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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 16 Classic**

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

(€ 0123

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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

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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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Secrecy: Restrict



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 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

(€ 0123

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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

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

Wu Shaoiie

CEO

Wang Zhiqiang
TQM Director

Issued: September 18, 2019

File No: N16-MRI01Q-DM040 Temp. No: NT3-009-001-R02 File Version: 5.0

Temp. Version: 4.0

Secrecy: Restrict



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

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

(€ 0123

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Shenyang, Liaoning, China 110167

Wu Shaojie

Wang Zhiqiang

Issued: 2019-09-19

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