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Neusoft 东软医疗

EC Declaration of Conformity

Manufacturer:

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

whose single Authorized Representative:

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

CE 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

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