



EC Declaration of Conformity

Conformity to DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 1998 on in vitro diagnostic medical devices

Manufacturer: Greiner Bio-One GmbH
Bad Haller Straße 32
4550 Kremsmünster
Austria

Production Location: ELITechGroup B.V.
Van Rensselaerweg 4
6956 AV Spankeren
Netherlands

Product / Product Group: Sed Rate Devices
(for details please refer to page 2)

Classification: Other device (all devices except Annex II and except self-testing devices)

GMDN Code(s): (for details please refer to page 2)

We herewith declare under our sole responsibility that the above mentioned products meet the provisions of the above EC Council Directive and the applicable standards. All supporting documentations are retained under the premises of the manufacturer.

Conformity Assessment procedure acc. to Annex III of the Directive 98/79/EC of the European Parliament and of the Council on in vitro diagnostic medical devices.

Standards:

Refer to the List of applicable (harmonized) standards in the Technical Documentation.

Kremsmünster, 23.07.2019



Signature: _____

Georg Sambs
Reg. Affairs Manager





PRODUCT GROUP	Product name - detailed product description	Item numbers	GMDN Code
Sed Rate Devices (MultiMixer)	VACUETTE® MultiMixer for VACUETTE® Tubes Racks not included	836577	16384
Sed Rate Devices	Sed Rate Screener 100/II (SRS 100/II) incl. software (G2S140BO, vers. 1.4) automatic ESR reader with integrated printer (for 100 tubes)	836580	56691
Sed Rate Devices	Sed Rate Screener 20/II (SRS 20/II) incl. software (G2P140BO, vers. 1.4) automatic ESR reader with integrated printer (for 20 tubes)	836587	56691
Sed Rate Devices	Sed Rate Timer 10/II (SRT 10/II) incl. software (G2M110BO, vers. 1.1) automatic ESR reader (for 10 tubes)	836592	56691

EC Declaration of Conformity

Conformity to COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices

Manufacturer: Greiner Bio-One GmbH
Bad Haller Straße 32
4550 Kremsmünster
Austria

Production Location: Nipro Medical Industries Ltd.
Tatebayashi Plant 2-19-64, Matsubara,
Tatebayashi-shi, Gunma, 374-8518
Japan

Product / Product Group: VACUETTE® VISIO PLUS Needles
(for details please refer to page 2)

Classification: Class IIa, according to COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices, Annex IX, III. Classification, 2.2, rule 6 without application of exceptions

GMDN Code(s): 35209

We herewith declare under our sole responsibility that the above mentioned products meet the provisions of the above EC Council Directive and the applicable standards. All supporting documentations are retained under the premises of the manufacturer.

Conformity Assessment procedure acc. to Annex V and Annex VII of the Council Directive 93/42/EEC concerning medical devices

TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 München
G2 029670 0035 Rev. 00, valid until 26 May 2024

Standards:
Refer to the List of applicable (harmonized) standards in the Technical Documentation.

Kremsmünster, 24.09.2019



Signature: _____

Georg Sambs
Reg. Affairs Manager



PRODUCT GROUP	Product name - detailed product description	Item numbers
VACUETTE® VISIO PLUS Needles	VACUETTE® VISIO PLUS Needle 21G x 1 1/2" green, sterile, not made with natural rubber latex 0.8 x 38 mm	450040
VACUETTE® VISIO PLUS Needles	VACUETTE® VISIO PLUS Needle 21G x 1 1/2" green, sterile, not made with natural rubber latex 0.80 x 38 mm, Russia	450040RU
VACUETTE® VISIO PLUS Needles	VACUETTE® VISIO PLUS Needle 22G x 1 1/2" black, sterile, not made with natural rubber latex 0.7 x 38 mm	450041
VACUETTE® VISIO PLUS Needles	VACUETTE® VISIO PLUS Needle 22G x 1 1/2" black, sterile, not made with natural rubber latex 0.70 x 38 mm, Russia	450041RU
VACUETTE® VISIO PLUS Needles	VACUETTE® VISIO PLUS Needle 21G x 1" green, sterile, not made with natural rubber latex 0.8 x 25 mm	450042
VACUETTE® VISIO PLUS Needles	VACUETTE® VISIO PLUS Needle 21G x 1" green, sterile, not made with natural rubber latex 0.8 x 25 mm, Russia	450042RU
VACUETTE® VISIO PLUS Needles	VACUETTE® VISIO PLUS Needle 22G x 1" black, sterile, not made with natural rubber latex 0.7 x 25 mm	450043
VACUETTE® VISIO PLUS Needles	VACUETTE® VISIO PLUS Needle 22G x 1" black, sterile, not made with natural rubber latex 0.7 x 25 mm, Russia	450043RU
VACUETTE® VISIO PLUS Needles	VACUETTE® VISIO PLUS Needle 21G x 1 1/4" green, sterile, not made with natural rubber latex 0.8 x 32 mm	450044
VACUETTE® VISIO PLUS Needles	VACUETTE® VISIO PLUS Needle 22G x 1 1/4" black, sterile, not made with natural rubber latex 0.7 x 32 mm	450045



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Bad Haller Straße 32
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Production Location: Greiner Bio-One GmbH
Bad Haller Straße 32
4550 Kremsmünster
Austria

Product / Product Group: Tube Holder
(for details please refer to page 2)

Classification: Class I, according to COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices, Annex IX, III. Classification, 1.1., rule 1

GMDN Code(s): 37566

We herewith declare under our sole responsibility that the above mentioned products meet the provisions of the above EC Council Directive and the applicable standards. All supporting documentations are retained under the premises of the manufacturer.

Conformity Assessment procedure acc. to Annex VII of the Council Directive 93/42/EEC concerning medical devices.

Standards:
Refer to the List of applicable (harmonized) standards in the Technical Documentation.

Product Group: (for details please refer to page 2)

Classification: Class I, according to COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices, Annex IX, III. Classification, 1.1., rule 1

GMDN Code(s): 37566

We herewith declare under our sole responsibility that the above mentioned products meet the provisions of the above EC Council Directive and the applicable standards. All supporting documentations are retained under the premises of the manufacturer.

Conformity Assessment procedure acc. to Annex VII of the Council Directive 93/42/EEC concerning medical devices.

Kremsmünster, 29.07.2019

Standards:
Refer to the List of applicable (harmonized) standards in the Technical Documentation.



Signature: _____

Georg Sambs
Reg. Affairs Manager





PRODUCT GROUP	Product Name - Details or Price	Unit
Tube Holder	Standard Tube Holder	each
Tube Holder	Sterile Tube Holder 100 pieces per box	each box
Tube Holder	Breathero Tube Holder Japan 100 pieces per box	each box
Tube Holder	Openry Quick Release Holder	each
Tube Holder	VACUETTE® QUICK SHIELD Safety Tube Holder	each