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greiner BIO-ONE

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

greiner QM bio-one

Signature: .....

Georg Sambs
Reg. Affairs Manager

«BECOR» S.R.L. PENTRU CONTRACTE

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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

REPUBLICA MOLDOVA, mun. CHISINAU IDNO 1003600060828 I.M. «BECOR» PENTRU CONTRACTE SOCIETATEA CU RASPUNDERE LIMITATA

CE 0123

greiner BIO-ONE

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

greiner QM bio-one

Signature: .....

Georg Sambs
Reg. Affairs Manager

REPUBLICA MOLDOVA, mun. CHISINAU IDNO 1003600060828 I.M. «BECOR» S.R.L. PENTRU CONTRACTE CU RASPUNDERE LIMITATA BECOR

CE 0123

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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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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:	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.

Kremsmünster, 29.07.2019

greiner QM bio-one

Signature: .....

Georg Sambs
Reg. Affairs Manager

REPUBLICA MOLDOVA, mun. CHISINAU IDNO 1006600060828 I.M. «BECOR» S.R.L. PENTRU CONCRETE FUNDERE LIMITATA

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PRODUCT GROUP	Product name - detailed product description	Item numbers
Tube Holder	Standard Tube Holder 10 pcs. per bag	450201
Tube Holder	Standard Tube Holder 100 pcs. per bag	450209
Tube Holder	Standard Tube Holder Japan 100 pcs. per bag	450209JP
Tube Holder	Speedy Quick Release Holder	450212
Tube Holder	VACUETTE® QUICKSHIELD Safety Tube Holder	450230