

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, 22.03.2021



Signature: 
Georg Sambs
Quality Manager GBO AT

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 0.80 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 0.70 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