CE 0123

EU Declaration of Conformity

to REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices

Manufacturer:	Greiner Bio-One GmbH Bad Haller Straße 32 4550 Kremsmünster Austria	SRN: AT-MF-000024608
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)	
Basic UDI-DI (GMN):	912001757G0000076A8	
Intended purpose:	VACUETTE® VISIO PLUS Blood Collection Needles are designed for use in the daily blood collection routine when delegated by a qualified practitioner. The flashback window is situated in the transparent part of the cannula hub, which assists the user to recognise successful vein penetration. They are for single-use only and should only be used by adequately trained healthcare personnel in accordance with the Instructions for Use. The product is a sterile medical device intended to be used in healthcare settings such as hospitals, clinics, and laboratories. The device is suitable for use in pediatric, adult and elderly patients requiring venous blood collection. In combination with tube holders and one or multiple blood collection tubes the needle is inserted into a peripheral vein suitable for venipuncture to establish venous access, allowing for blood collection for in vitro diagnostic testing.	
Classification:	Class IIa according to Regulation (EU) 2017/745 of the european parliament and of the council of 5 April 2017 on medical devices, Annex VIII - Chapter III Classification Rules - 5.2. Rule 6 without application of exceptions	
GMDN Code(s):	35209	

We herewith declare under our sole responsibility that the products specified above meet the provisions of the above-mentioned Regulation. All supporting documentation is retained under the premises of the manufacturer.

Conformity Assessment procedure according to Annex IX and Annex IV of the Regulation (EU) 2017/745.

TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 Munich
G15 029670 0040 Rev. 00, valid until 12 October 2030

Standards / common specifications:
Refer to the list of applicable (harmonized) standards and common specifications in the Technical

Kremsmünster, 26.03.2026

Daniel Stocker
Electronically signed by: Daniel Stocker
Reason: I agree to sign.
Date: Mar 27, 2026 08:11:24 GMT+1

Daniel Stocker
PRRC
Person Responsible for Regulatory Compliance

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greiner BIO-ONE

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