CE 0123

greiner BIO-ONE

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® Multiple Use Drawing Needles (for details please refer to page 2)	
Basic UDI-DI (GMN):	912001757G0000075A6	
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 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 Documentation.

Kremsmünster, 13.10.2025

greiner QM bio-one

Johann Sperneder
PRRC
Person Responsible for Regulatory Compliance

Product Group	Product name - detailed product description	Item numbers
VACUETTE® Multiple Use Drawing Needles	VACUETTE® Multiple Use Drawing Needle 22G x 1 1/4" black, sterile, not made with natural rubber latex 0.7 x 32 mm	450061
VACUETTE® Multiple Use Drawing Needles	VACUETTE® Multiple Use Drawing Needle 21G x 1 1/4" green, sterile, not made with natural rubber latex 0.8 x 32 mm	450062
VACUETTE® Multiple Use Drawing Needles	VACUETTE® Multiple Use Drawing Needle 20G x 1 1/4" yellow, sterile, not made with natural rubber latex 0.9 x 32 mm	450063
VACUETTE® Multiple Use Drawing Needles	VACUETTE® Multiple Use Drawing Needle 22G x 1" black, sterile, not made with natural rubber latex 0.7 x 25 mm	450071
VACUETTE® Multiple Use Drawing Needles	VACUETTE® Multiple Use Drawing Needle 21G x 1" green, sterile, not made with natural rubber latex 0.8 x 25 mm	450072
VACUETTE® Multiple Use Drawing Needles	VACUETTE® Multiple Use Drawing Needle 20G x 1" yellow, sterile, not made with natural rubber latex 0.9 x 25 mm	450073
VACUETTE® Multiple Use Drawing Needles	VACUETTE® Multiple Use Drawing Needle 22G x 1 1/2" black, sterile, not made with natural rubber latex 0.7 x 38 mm	450075
VACUETTE® Multiple Use Drawing Needles	VACUETTE® Multiple Use Drawing Needle 22G x 1 1/2" black, sterile, not made with natural rubber latex 0.70 x 38 mm, Russia	450075RU
VACUETTE® Multiple Use Drawing Needles	VACUETTE® Multiple Use Drawing Needle 21G x 1 1/2" green, sterile, not made with natural rubber latex 0.8 x 38 mm	450076
VACUETTE® Multiple Use Drawing Needles	VACUETTE® Multiple Use Drawing Needle 21G x 1 1/2" green, sterile, not made with natural rubber latex 0.80 x 38 mm, Russia	450076RU
VACUETTE® Multiple Use Drawing Needles	VACUETTE® Multiple Use Drawing Needle 20G x 1 1/2" yellow, sterile, not made with natural rubber latex 0.9 x 38 mm	450077
VACUETTE® Multiple Use Drawing Needles	VACUETTE® Multiple Use Drawing Needle 20G x 1 1/2" yellow, sterile, not made with natural rubber latex 0.90 x 38 mm, Russia	450077RU