

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 SRN: AT-MF-000024608
Bad Haller Straße 32
4550 Kremsmünster
Austria

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

Product / VACUETTE® Multiple Use Drawing Needles
Product Group: (for details please refer to page 2)

Basic UDI-DI (GMN): 912001757G0000075A6

Intended Purpose: VACUETTE® Multiple Use Drawing Needles are for use in venous blood collection. The product is a sterile, single-use medical device intended to be used exclusively by healthcare professionals trained in phlebotomy procedures 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 Documentation.

Kremsmünster, 03.06.2026

Daniel Stocker Electronically signed by: Daniel Stocker
Reason: I agree to sign.
Date: Jun 3, 2026 12:03:51 GMT+2

Daniel Stocker
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