

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® Multiple Use Drawing 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® 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 |