

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 (Thailand) Corporation Ltd.
10/2 Moo 8 Bangnomko, Sena,
Phra Nakhon Si Ayutthaya 13110
Thailand

Product / Product Group: Blood Collection Sets
(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, 2.3, rule 7 without application of exceptions

GMDN Code(s): 65416

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 0037 Rev. 00, valid until 26 May 2024

Standards:
Refer to the List of applicable (harmonized) standards in the Technical Documentation.

Kremsmünster, 26.04.2021



Signature: 
Georg Sambs
Quality Manager GBO AT

PRODUCT GROUP	Product name - detailed product description	Item numbers
Blood Collection Sets	Blood Collection/Infusion Set 21G x 3/4" tubing length 4" (10 cm), single-packed, sterile, not made with natural rubber latex	450059
Blood Collection Sets	Blood Collection Set + Luer Adapter 21G x 3/4" tubing length 4" (10 cm), single-packed, sterile, not made with natural rubber latex	450064
Blood Collection Sets	Blood Collection Set + Luer Adapter 21G x 3/4" tubing length 12" (30 cm), single-packed, sterile, not made with natural rubber latex	450065
Blood Collection Sets	Blood Collection Set + Luer Adapter 21G x 3/4" tubing length 7 1/2" (19 cm), single-packed, sterile, not made with natural rubber latex	450066
Blood Collection Sets	Blood Collection Set + Luer Adapter 23G x 3/4" tubing length 7 1/2" (19 cm), single-packed, sterile, not made with natural rubber latex	450089
Blood Collection Sets	Blood Collection/Infusion Set 21G x 3/4" tubing length 7 1/2" (19 cm), single-packed, sterile, not made with natural rubber latex	450153
Blood Collection Sets	Blood Collection/Infusion Set 23G x 3/4" tubing length 7 1/2" (19 cm), single-packed, sterile, not made with natural rubber latex	450155
Blood Collection Sets	Blood Collection Set + Luer Adapter 23G x 3/4" tubing length 12" (30 cm), single-packed, sterile, not made with natural rubber latex	450159
Blood Collection Sets	Blood Collection Set + Holder 21G x 3/4" tubing length 7 1/2" (19 cm), single-packed, sterile, not made with natural rubber latex	450371
Blood Collection Sets	Blood Collection Set + Holder 23G x 3/4" tubing length 7 1/2" (19 cm), single-packed, sterile, not made with natural rubber latex	450373
Blood Collection Sets	Blood Collection Set + Holder 25G x 3/4" tubing length 7 1/2" (19 cm), single-packed, sterile, not made with natural rubber latex	450375