

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: SAFETY Blood Collection Sets
(for details please refer to page 2-5)

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, 21.03.2024



Signature: 
Georg Sambs
Director Quality Management

PRODUCT GROUP	Product name - detailed product description	Item numbers
SAFETY Blood Collection Sets	SAFETY 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 (1,000 pcs.)	450081
SAFETY Blood Collection Sets	SAFETY 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 (1,080 pcs.)	450081V1
SAFETY Blood Collection Sets	SAFETY 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 (1,000 pcs.)	450082
SAFETY Blood Collection Sets	SAFETY 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 (1,080 pcs.)	450082V1
SAFETY Blood Collection Sets	SAFETY Blood Collection Set + Luer Adapter 21G x 3/4" tubing length 4" (10 cm), single-packed, sterile, not made with natural rubber latex (1,000 pcs.)	450083
SAFETY Blood Collection Sets	SAFETY Blood Collection Set + Luer Adapter 21G x 3/4" tubing length 4" (10 cm), single-packed, sterile, not made with natural rubber latex (1,080 pcs.)	450083V1
SAFETY Blood Collection Sets	SAFETY Blood Collection Set + Luer Adapter 23G x 3/4" tubing length 4" (10 cm), single-packed, sterile, not made with natural rubber latex (1,000 pcs.)	450084
SAFETY Blood Collection Sets	SAFETY Blood Collection Set + Luer Adapter 23G x 3/4" tubing length 4" (10 cm), single-packed, sterile, not made with natural rubber latex (1,080 pcs.)	450084V1
SAFETY Blood Collection Sets	SAFETY Blood Collection Set + Holder 21G x 3/4" tubing length 7 1/2" (19 cm), single-packed, sterile, not made with natural rubber latex (240 pcs.)	450085
SAFETY Blood Collection Sets	SAFETY Blood Collection Set + Holder 21G x 3/4" tubing length 7 1/2" (19 cm), single-packed, sterile, not made with natural rubber latex (420 pcs.)	450085V1
SAFETY Blood Collection Sets	SAFETY Blood Collection Set + Holder 23G x 3/4" tubing length 7 1/2" (19 cm), single-packed, sterile, not made with natural rubber latex (240 pcs.)	450086

PRODUCT GROUP	Product name - detailed product description	Item numbers
SAFETY Blood Collection Sets	SAFETY Blood Collection Set + Holder 23G x 3/4" tubing length 7 1/2" (19 cm), single-packed, sterile, not made with natural rubber latex (420 pcs.)	450086V1
SAFETY Blood Collection Sets	SAFETY Blood Collection Set + Holder 21G x 3/4" tubing length 4" (10 cm), single-packed, sterile, not made with natural rubber latex (240 pcs.)	450087
SAFETY Blood Collection Sets	SAFETY Blood Collection Set + Holder 21G x 3/4" tubing length 4" (10 cm), single-packed, sterile, not made with natural rubber latex (420 pcs.)	450087V1
SAFETY Blood Collection Sets	SAFETY Blood Collection Set + Holder 23G x 3/4" tubing length 4" (10 cm), single-packed, sterile, not made with natural rubber latex (240 pcs.)	450088
SAFETY Blood Collection Sets	SAFETY Blood Collection Set + Holder 23G x 3/4" tubing length 4" (10 cm), single-packed, sterile, not made with natural rubber latex (420 pcs.)	450088V1
SAFETY Blood Collection Sets	SAFETY Blood Collection/Infusion Set 25G x 3/4" tubing length 7 1/2" (19 cm), single-packed, sterile, not made with natural rubber latex (1,000 pcs.)	450090
SAFETY Blood Collection Sets	SAFETY Blood Collection/Infusion Set 25G x 3/4" tubing length 7 1/2" (19 cm), single-packed, sterile, not made with natural rubber latex (1,080 pcs.)	450090V1
SAFETY Blood Collection Sets	SAFETY Blood Collection/Infusion Set 21G x 3/4" tubing length 7 1/2" (19 cm), single-packed, sterile, not made with natural rubber latex (1,000 pcs.)	450091
SAFETY Blood Collection Sets	SAFETY Blood Collection/Infusion Set 21G x 3/4" tubing length 7 1/2" (19 cm), single-packed, sterile, not made with natural rubber latex (1,080 pcs.)	450091V1
SAFETY Blood Collection Sets	SAFETY Blood Collection/Infusion Set 23G x 3/4" tubing length 7 1/2" (19 cm), single-packed, sterile, not made with natural rubber latex (1,000 pcs.)	450092
SAFETY Blood Collection Sets	SAFETY Blood Collection/Infusion Set 23G x 3/4" tubing length 7 1/2" (19 cm), single-packed, sterile, not made with natural rubber latex (1,080 pcs.)	450092V1
SAFETY Blood Collection Sets	SAFETY Blood Collection/Infusion Set 23G x 3/4" tubing length 4" (10 cm), single-packed, sterile, not made with natural rubber latex	450094

PRODUCT GROUP	Product name - detailed product description	Item numbers
SAFETY Blood Collection Sets	SAFETY Blood Collection Set + Luer Adapter 21G x 3/4" tubing length 12" (30 cm), single-packed, sterile, not made with natural rubber latex (1,000 pcs.)	450095
SAFETY Blood Collection Sets	SAFETY Blood Collection Set + Luer Adapter 21G x 3/4" tubing length 12" (30 cm), single-packed, sterile, not made with natural rubber latex (1,080 pcs.)	450095V1
SAFETY Blood Collection Sets	SAFETY Blood Collection Set + Luer Adapter 23G x 3/4" tubing length 12" (30 cm), single-packed, sterile, not made with natural rubber latex (1,000 pcs.)	450096
SAFETY Blood Collection Sets	SAFETY Blood Collection Set + Luer Adapter 23G x 3/4" tubing length 12" (30 cm), single-packed, sterile, not made with natural rubber latex (1,080 pcs.)	450096V1
SAFETY Blood Collection Sets	SAFETY Blood Collection Set + Luer Adapter 25G x 3/4" tubing length 12" (30 cm), single-packed, sterile, not made with natural rubber latex (1,000 pcs.)	450099
SAFETY Blood Collection Sets	SAFETY Blood Collection Set + Luer Adapter 25G x 3/4" tubing length 12" (30 cm), single-packed, sterile, not made with natural rubber latex (1,080 pcs.)	450099V1
SAFETY Blood Collection Sets	SAFETY Blood Collection Set + Holder 21G x 3/4" tubing length 12" (30 cm), single-packed, sterile, not made with natural rubber latex (240 pcs.)	450160
SAFETY Blood Collection Sets	SAFETY Blood Collection Set + Holder 21G x 3/4" tubing length 12" (30 cm), single-packed, sterile, not made with natural rubber latex (420 pcs.)	450160V1
SAFETY Blood Collection Sets	SAFETY Blood Collection Set + Holder 23G x 3/4" tubing length 12" (30 cm), single-packed, sterile, not made with natural rubber latex (240 pcs.)	450161
SAFETY Blood Collection Sets	SAFETY Blood Collection Set + Holder 23G x 3/4" tubing length 12" (30 cm), single-packed, sterile, not made with natural rubber latex (420 pcs.)	450161V1
SAFETY Blood Collection Sets	SAFETY Blood Collection/Infusion Set 21G x 3/4" tubing length 12" (30 cm), single-packed, sterile, not made with natural rubber latex (1,000 pcs.)	450191

SAFETY Blood Collection Sets	SAFETY Blood Collection/Infusion Set 21G x 3/4" tubing length 12" (30 cm), single-packed, sterile, not made with natural rubber latex (1,080 pcs.)	450191V1
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