

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 Str. 32
4550 Kremsmünster
AUSTRIA

Production Location: Nipro (Thailand) Corporation Limited
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 2-3)

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 Codes 58490

We herewith declare under our sole responsibility that the above mentioned products meet the provisions of the following EC Council Directives and 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 17 09 29670 031, valid until 13 October 2022


Standards:

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

Kremsmünster, 07.03.2018



Signature:


Georg Sambs
Reg. Affairs Manager

PRODUCT GROUP	Product name - detailed product description	Item numbers
SAFETY Blood Collection Sets	SAFETY Blood Collection Set + Holder 25G x 3/4" tubing length 12" (30 cm), single-packed, sterile, not made with natural rubber latex	450080
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	450081
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	450082
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	450083
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	450084
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	450085
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	450086
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	450087
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	450088
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	450090
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	450091

PRODUCT GROUP	Product name - detailed product description	Item numbers
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	450092
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
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	450095
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	450096
SAFETY Blood Collection Sets	SAFETY Blood Collection Set + HOLDEX® 21G x 3/4" tubing length 12" (30 cm), single-packed, sterile	450097
SAFETY Blood Collection Sets	SAFETY Blood Collection Set + HOLDEX® 23G x 3/4" tubing length 12" (30 cm), single-packed, sterile	450098
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	450099
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	450160
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	450161
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	450191
SAFETY Blood Collection Sets	SAFETY Blood Collection/Infusion Set 23G x 3/4" tubing length 12" (30 cm), single-packed, sterile, not made with natural rubber latex	450192