

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

Product / SAFETY Blood Collection/Infusion Sets
Product Group: (for details please refer to page 2-3)

Basic UDI-DI (GMN): 912001757G0000077AA

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 - 5.3. Rule 7 without application of exceptions

GMDN Code(s): 65416

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 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, 13.10.2025


Daniel Stocker
PRRC

Person Responsible for Regulatory Compliance

Product Group	Product name - detailed product description	Item numbers
SAFETY Blood Collection/Infusion 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/Infusion 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/Infusion 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/Infusion 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/Infusion 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/Infusion 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/Infusion 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/Infusion 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/Infusion 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/Infusion 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/Infusion 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

Product Group	Product name - detailed product description	Item numbers
SAFETY Blood Collection/Infusion 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/Infusion 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/Infusion 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/Infusion 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/Infusion 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/Infusion 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