

**ES Prohlášení o shodě**

Shoda se SMĚRNICÍ RADY 93/45/EHS ze dne 14. června 1993 o zdravotnických prostředcích

Výrobce:	Greiner Bio-One GmbH Bad Haller Strasse 32 4550 Kremsmünster Rakousko
Místo výroby:	Nipro Medical Industries Ltd. Tatebayashi Plant 2-19-64 , Matsubara Tatebayashi -shi, Gunma, 374-8518 Japonsko
Výrobek / Výrobová skup.:	VACUETTE® Multiple Use Drawing Needles (podrobné informace najdete na str. 2)
Klasifikace:	Třída IIa podle SMĚRNICE RADY 93/45/EHS ze dne 14. června 1993 o zdravotnických prostředcích Příloha IX, III. Klasifikace, 2.2, pravidlo 6 bez použití výjimek
GMDN kód/y:	35209

Tímto prohlašujeme výhradně na vlastní odpovědnost, že výše uvedené výrobky splňují ustanovení výše uvedené Směrnice ES Rady a příslušné normy. Veškerá podpůrná dokumentace je uchovávána výrobcem v jeho prostorách.

Postup posouzení shody podle Přílohy V a Přílohy VII směrnice 93/45/EHS o zdravotnických prostředcích.

TÜV SÜD Product Service GmbH, Ridlerstrasse 65, 80339 Mnichov  
G2S 029670 0035 Rev. 00, platí do 26. května 2024

Normy:

Viz seznam příslušných (harmonizovaných) norem v technické dokumentaci.

Kremsmünster, 22.03.2023



Podpis: *nečitelné*  
Georg Sambs  
Ředitel kvality GBO AT

## 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