

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: Greiner Bio-One GmbH
Bad Haller Straße 32
4550 Kremsmünster
Austria

Product / Product Group: VACUETTE® QUICKSHIELD Complete
(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): 58284

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 0038 Rev. 00, valid until 26 May 2024

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

Kremsmünster, 22.03.2024



Signature: 
Georg Sambs
Director Quality Management

PRODUCT GROUP	Product name - detailed product description	Item numbers
VACUETTE® QUICKSHIELD Complete	VACUETTE® QUICKSHIELD Complete 22G x 1 1/2" single-packed, sterile 0.70 x 38 mm	450206V1
VACUETTE® QUICKSHIELD Complete	VACUETTE® QUICKSHIELD Complete PLUS 22G x 1" single-packed, sterile 0.70 x 25 mm	450226V1
VACUETTE® QUICKSHIELD Complete	VACUETTE® QUICKSHIELD Complete PLUS 22G x 1 1/2" single-packed, sterile 0.70 x 38 mm	450228V1
VACUETTE® QUICKSHIELD Complete	VACUETTE® QUICKSHIELD Complete 22G x 1" single-packed, sterile 0.70 x 25 mm	450234V1
VACUETTE® QUICKSHIELD Complete	VACUETTE® QUICKSHIELD Complete PLUS 21G x 1" single-packed, sterile 0.80 x 25 mm	450235V1
VACUETTE® QUICKSHIELD Complete	VACUETTE® QUICKSHIELD Complete 21G x 1 1/2" single-packed, sterile 0.80 x 38 mm	450237V1
VACUETTE® QUICKSHIELD Complete	VACUETTE® QUICKSHIELD Complete 21G x 1" single-packed, sterile 0.80 x 25 mm	450238V1
VACUETTE® QUICKSHIELD Complete	VACUETTE® QUICKSHIELD Complete PLUS 21G x 1 1/2" single-packed, sterile 0.80 x 38 mm	450239V1