CE 0123

greiner BIO-ONE

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 Bad Haller Straße 32 4550 Kremsmünster Austria	SRN: AT-MF-000024608	
Production Location:	Greiner Bio-One GmbH Bad Haller Straße 32 4550 Kremsmünster Austria	and	Plant Rainbach Gewerbepark 2 4261 Rainbach Austria
Product / Product Group:	VACUETTE® QUICKSHIELD Complete (for details please refer to page 2)		
Basic UDI-DI (GMN):	912001757G00000809X 912001757G00000819Z (PLUS)		
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 - 5.2. Rule 6 without application of exceptions		
GMDN Code(s):	58284		

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

greiner QM bio-one

Johann Sperneder
PRRC
Person Responsible for Regulatory Compliance

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