

EC Declaration of Conformity

Conformity to DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 1998 on in vitro diagnostic 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® Blood Transfer Unit
(for details please refer to page 2)

Classification: Other device (all devices except Annex II and except self-testing devices)

GMDN Code(s): 58136

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 III of the Directive 98/79/EC of the European Parliament and of the Council on in vitro diagnostic medical devices.

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

Kremsmünster, 14.06.2019



Signature:



Georg Sams
Reg. Affairs Manager



PRODUCT GROUP	Product name - detailed product description	Item numbers
VACUETTE® Blood Transfer Unit	VACUETTE® Blood Transfer Unit PP single-packed, sterile	450225