

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

Product / VACUETTE® Blood Culture Holder  
Product Group: (for details please refer to page 2)

Basic UDI-DI (GMN): 912001757G00000049F

Classification: Class I 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 - 4.1. Rule 1

GMDN Code(s): 37566

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.

Standards / common specifications:

Refer to the list of applicable (harmonized) standards and common specifications in the Technical  
Documentation.

Kremsmünster, 24.03.2023



  
Georg Sambs  
Quality Manager Greiner Bio-One Austria



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Product Group	Product name - detailed product description	Item numbers
VACUETTE® Blood Culture Holder	VACUETTE® Blood Culture Holder non-sterile	450181