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:	Nipro Medical Industries Ltd. Tatebayashi Plant 2-19-64, Matsubara, Tatebayashi-shi, Gunma, 374-8518 Japan	
Product / Product Group:	VACUETTE® Luer Adapter (for details please refer to page 2)	
Basic UDI-DI (GMN):	912001757G0000074A4	
Classification:	Class Is 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):	60579	

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

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Product Group	Product name - detailed product description	Item numbers
VACUETTE® Luer Adapter	VACUETTE® Luer Adapter 20G sterile, not made with natural rubber latex	450070