CE 0123

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	
Intended purpose:	The VACUETTE® Luer Adapter is for use in venous blood collection with attached butterfly needle or luer needle. This device is to be used by properly trained healthcare professionals only in accordance with these instructions. The VACUETTE® Luer Adapter is a sterile, single-use, non-invasive medical device. It is intended to be used in combination with tube holders and peripheral venous access devices including a female connector in combination with one or multiple blood collection tubes allowing for blood collection for in vitro diagnostic testing in healthcare settings such as hospitals, clinics, and laboratories. The device is suitable for use in the general population.	
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 IX and 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, 23.01.2026

Daniel Stocker

Electronically signed by: Daniel Stocker
Reason: I agree to sign.
Date: Jan 23, 2026 14:22:19 GMT+1

Daniel Stocker
PRRC
Person Responsible for Regulatory Compliance

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