CE

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	Greiner Bio-One North America Inc. 4238 Capital Drive, Monroe NC 28110 United States of America
	Greiner Bio-One Brasil Produtos Medicos Hospitalares Ltda. Av. Affonso Pansan no. 1.967 13473-620, Villa Bertini Americana, Sao Paulo Brasil	Greiner Bio-One (Thailand) Ltd. 700/172 Moo.1 Amata Nakorn Industrial Estate Tambon Bankao Amphur Phanthong Chonburi 20160 Thailand
Product / Product Group:	Tube Holder (for details please refer to page 2)	
Intended Use:	The Standard Tube Holder is intended to be used only with VACUETTE® Multiple Use Drawing Needles and VACUETTE® VISIO PLUS Needles. Together with the VACUETTE® Blood Collection Tubes they are used as a system in routine venipuncture procedures. This device is to be used by properly trained healthcare professionals only in accordance with the instructions.	
Basic UDI-DI (GMN):	(for details please refer to page 2)	
Classification:	Class I according to Regulation (EU) 2017/745 of the europeän 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, 25.11.2025

greiner QM bio-one

Daniel Stocker
PRRC
Person Responsible for Regulatory Compliance

CE

greiner BIO-ONE

Product Group	Product name - detailed product description	Item numbers	Basic UDI-DI (GMN)
Tube Holder	Standard Tube Holder 10 pcs. per bag	450201	912001757G000000199
Tube Holder	Standard Tube Holder 100 pcs. per bag	450209	912001757G000000199
Tube Holder	Speedy Quick Release Holder	450212	912001757G00000039D
Tube Holder	VACUETTE® QUICKSHIELD Safety Tube Holder	450230	912001757G00000029B