CE

greiner BIO-ONE

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	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:	VACUETTE® TUBES (for details please refer to page 2-41)	
Classification:	Other device (all devices except Annex II and except self-testing devices)	
GMDN Code(s):	(for details please refer to page 2-41)	

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, 23.06.2020

greiner QM bio-one

Signature: .....

Georg Sambs
Quality Manager GBO AT

Digitally signed by Lazari Cristina
Date: 2022.11.16 15:24:33 EET
Reason: MoldSign Signature
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