

## 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  
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4238 Capital Drive, Monroe  
NC 28110  
United States of America

Greiner Bio-One Brasil  
Produtos Medicos  
Hospitalares Ltda.  
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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



Signature:   
Georg Sambs  
Quality Manager GBO AT