

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 Greiner Bio-One GmbH
Location: 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 / VACUETTE® TUBES
Product Group: (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