

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



Signature: 
Georg Sambs
Quality Manager GBO AT



VACUETTE® Tube Group	Additive	Product name - detailed product description	Item No.	GMDN
K2E	K2EDTA	VACUETTE® TUBE 6 ml K2E K2EDTA 13x100 pink cap-pink ring, transparent label, non-ridged	456280	43865
K2E	K2EDTA	VACUETTE® TUBE 4 ml K2E K2EDTA 13x75 pink cap-black ring, GeT barcode label, non-ridged	484506	43865
K2E	K2EDTA	VACUETTE® TUBE 4 ml K2E K2EDTA 13x75 lavender cap-black ring, GeT barcode label, non-ridged	484507	43865
K2E	K2EDTA	VACUETTE® TUBE 3 ml K2E K2EDTA 13x75 lavender cap-black ring, GeT barcode label, PREMIUM	484526	43865
K2E	K2EDTA	VACUETTE® TUBE 9 ml K2E K2EDTA 16x100 lavender cap-black ring, GeT Bi- Barcode label, non-ridged	495045	43865
K2E	K2EDTA Sep	VACUETTE® TUBE 3.5 ml K2E K2EDTA Separator 13x75 lavender cap-yellow ring, non-ridged	454059	47587
K2E	K2EDTA Sep	VACUETTE® TUBE 3.5 ml K2E K2EDTA Separator 13x75 lavender cap-yellow ring, PREMIUM	454235	47587
K2E	K2EDTA Sep	VACUETTE® TUBE 3.5 ml K2E K2EDTA Separator 13x75 lavender cap-yellow ring, PREMIUM	454235P	47587
K2E	K2EDTA Sep	VACUETTE® TUBE 3.5 ml K2E K2EDTA Separator 13x75 white cap-yellow ring, non-ridged	454509P	47587
K2E	K2EDTA Sep	VACUETTE® TUBE 8 ml K2E K2EDTA Separator 16x100 white cap-yellow ring, non-ridged	455021	47587
K2E	K2EDTA Sep	VACUETTE® TUBE 8 ml K2E K2EDTA Separator 16x100 white cap-yellow ring, non-ridged, USA	455021P	47587
K2E	K2EDTA Sep	VACUETTE® TUBE 8 ml K2E K2EDTA Separator 16x100 lavender cap-yellow ring, non-ridged	455040	47587
K2E	K2EDTA Sep	VACUETTE® TUBE 8 ml K2E K2EDTA Separator 16x100 lavender cap-yellow ring, non-ridged, USA	455040P	47587
K2E	K2EDTA Sep	VACUETTE® TUBE 8 ml K2E K2EDTA Separator 16x100 lavender cap-yellow ring, non-ridged, China	455040CN	47587
K2E	K2EDTA Sep	VACUETTE® TUBE 5 ml K2E K2EDTA Separator 13x100 lavender cap-yellow ring, PREMIUM	456011	47587
K2E	K2EDTA Sep	VACUETTE® TUBE 5 ml K2E K2EDTA Separator 13x100 lavender cap-yellow ring, PREMIUM, China	456011CN	47587
K2E	K2EDTA Sep	VACUETTE® TUBE 4.5 ml K2E K2EDTA Separator 13x100 lavender cap-yellow ring, non-ridged, USA	456024P	47587