

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
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Austria

Production Greiner Bio-One GmbH
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4550 Kremsmünster
Austria

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700/172 Moo.1
Amata Nakorn Industrial Estate
Tambon Bankao
Amphur Phanthong
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Thailand

Product / VACUETTE® TUBES (Alternative Gel)
Product Group: (for details please refer to page 2-7)

Classification: Other device (all devices except Annex II and except self-testing devices)

GMDN Code(s): (for details please refer to page 2-7)

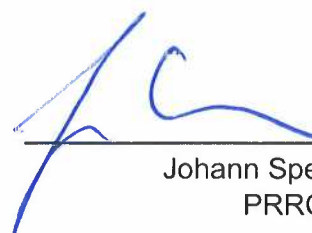
We herewith declare under our sole responsibility that the above mentioned products meet the provisions of the above EC Council Directive and the applicable standards. All supporting documentations are retained under the premises of the manufacturer.

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, 17.07.2025


Johann Speneder
PRRC

VACUETTE® Tube Group	Additive	Product name - detailed product description	Item No.	GMDN
CAT	Serum Sep Clot Activator	VACUETTE® TUBE 2.5 ml CAT Serum Separator Clot Activator 13x75 red cap-yellow ring, PREMIUM	454028A	41128
CAT	Serum Sep Clot Activator	VACUETTE® TUBE 3.5 ml CAT Serum Separator Clot Activator 13x75 red cap-yellow ring, non-ridged	454067A	41128
CAT	Serum Sep Clot Activator	VACUETTE® TUBE 3.5 ml CAT Serum Separator Clot Activator 13x75 red cap-yellow ring, PREMIUM	454071A	41128
CAT	Serum Sep Clot Activator	VACUETTE® TUBE 3.5 ml CAT Serum Separator Clot Activator 13x75 red cap-yellow ring, transparent label, non-ridged	454078A	41128
CAT	Serum Sep Clot Activator	VACUETTE® TUBE 2.5 ml CAT Serum Separator Clot Activator 13x75 yellow cap-white ring, black label, non-ridged	454205A	41128
CAT	Serum Sep Clot Activator	VACUETTE® TUBE 3.5 ml CAT Serum Separator Clot Activator 13x75 gold cap-gold ring, PREMIUM	454214A	41128
CAT	Serum Sep Clot Activator	VACUETTE® TUBE 3.5 ml CAT Serum Separator Clot Activator 13x75 red cap-yellow ring, non-ridged	454225A	41128
CAT	Serum Sep Clot Activator	VACUETTE® TUBE 3.5 ml CAT Serum Separator Clot Activator 13x75 gold cap-gold ring, black label, non-ridged	454228A	41128
CAT	Serum Sep Clot Activator	VACUETTE® TUBE 2.5 ml CAT Serum Separator Clot Activator 13x75 red cap-white ring, non-ridged	454243A	41128
CAT	Serum Sep Clot Activator	VACUETTE® TUBE 3.5 ml CAT Serum Separator Clot Activator 13x75 gold cap-white ring, black label, non-ridged	454253A	41128
CAT	Serum Sep Clot Activator	VACUETTE® TUBE 3.5 ml CAT Serum Separator Clot Activator 13x75 white cap-yellow ring, PREMIUM	454260A	41128
CAT	Serum Sep Clot Activator	VACUETTE® TUBE 3.5 ml CAT Serum Separator Clot Activator 13x75 royal blue cap-yellow ring, non-ridged	454263A	41128
CAT	Serum Sep Clot Activator	VACUETTE® TUBE 3.5 ml CAT Serum Separator Clot Activator 13x75 gold cap-black ring, non-ridged	454319A	41128

VACUETTE® Tube Group	Additive	Product name - detailed product description	Item No.	GMDN
CAT	Serum Sep Clot Activator	VACUETTE® TUBE 3.5 ml CAT Serum Separator Clot Activator 13x75 gold cap-gold ring, transparent label, non-ridged	454420A	41128
CAT	Serum Sep Clot Activator	VACUETTE® TUBE 4 ml CAT Serum Separator Clot Activator 16x100 red cap-yellow ring, non-ridged	455057A	41128
CAT	Serum Sep Clot Activator	VACUETTE® TUBE 8 ml CAT Serum Separator Clot Activator 16x100 red cap-yellow ring, non-ridged	455071A	41128
CAT	Serum Sep Clot Activator	VACUETTE® TUBE 8 ml CAT Serum Separator Clot Activator 16x100 gold cap-gold ring, non-ridged	455072A	41128
CAT	Serum Sep Clot Activator	VACUETTE® TUBE 7 ml CAT Serum Separator Clot Activator 16x100 red cap-yellow ring, non-ridged, double gel	455099A	41128
CAT	Serum Sep Clot Activator	VACUETTE® TUBE 5 ml CAT Serum Separator Clot Activator 13x100 white cap-yellow ring, black label, non-ridged	456004A	41128
CAT	Serum Sep Clot Activator	VACUETTE® TUBE 5 ml CAT Serum Separator Clot Activator 13x100 yellow cap-yellow ring, black label, non-ridged	456005A	41128
CAT	Serum Sep Clot Activator	VACUETTE® TUBE 5 ml CAT Serum Separator Clot Activator 13x100 royal blue cap-yellow ring, non-ridged	456006A	41128
CAT	Serum Sep Clot Activator	VACUETTE® TUBE 5 ml CAT Serum Separator Clot Activator 13x100 gold cap-gold ring, PREMIUM	456010A	41128
CAT	Serum Sep Clot Activator	VACUETTE® TUBE 5 ml CAT Serum Separator Clot Activator 13x100 gold cap-gold ring, black label, non-ridged	456018A	41128
CAT	Serum Sep Clot Activator	VACUETTE® TUBE 5 ml CAT Serum Separator Clot Activator 13x100 pink cap-yellow ring, non-ridged	456019A	41128
CAT	Serum Sep Clot Activator	VACUETTE® TUBE 5 ml CAT Serum Separator Clot Activator 13x100 red cap-yellow ring, transparent label, non-ridged	456069A	41128
CAT	Serum Sep Clot Activator	VACUETTE® TUBE 5 ml CAT Serum Separator Clot Activator 13x100 red cap-yellow ring, PREMIUM	456071A	41128

VACUETTE® Tube Group	Additive	Product name - detailed product description	Item No.	GMDN
CAT	Serum Sep Clot Activator	VACUETTE® TUBE 5 ml CAT Serum Separator Clot Activator 13x100 red cap-yellow ring, non-ridged	456073A	41128
CAT	Serum Sep Clot Activator	VACUETTE® TUBE 3.5 ml CAT Serum Separator Clot Activator 13x100 red cap-yellow ring, non-ridged	456214A	41128
CAT	Serum Sep Clot Activator	VACUETTE® TUBE 5 ml CAT Serum Separator Clot Activator 13x100 gold cap-gold ring, transparent label, non-ridged	456234A	41128
CAT	Serum Sep Clot Activator	VACUETTE® TUBE 3.5 ml CAT Serum Separator Clot Activator 13x75 red cap-yellow ring, transparent label, PREMIUM	474071A	41128
CAT	Serum Sep Clot Activator	VACUETTE® TUBE 3.5 ml CAT Serum Separator Clot Activator 13x75 gold cap-gold ring, transparent label, PREMIUM	474214A	41128
CAT	Serum Sep Clot Activator	VACUETTE® TUBE 5 ml CAT Serum Separator Clot Activator 13x100 gold cap-gold ring, transparent label, PREMIUM	476010A	41128
CAT	Serum Sep Clot Activator	VACUETTE® TUBE 5 ml CAT Serum Separator Clot Activator 13x100 red cap-yellow ring, transparent label, PREMIUM	476071A	41128
CAT	Serum Sep Clot Activator	VACUETTE® TUBE 2.5 ml CAT Serum Separator Clot Activator 13x75 yellow cap-white ring, black KOH barcode label, non-ridged	484485A	41128
CAT	Serum Sep Clot Activator	VACUETTE® TUBE 3.5 ml CAT Serum Separator Clot Activator 13x75 red cap-yellow ring, G-barcode label, non-ridged	484502A	41128
CAT	Serum Sep Clot Activator	VACUETTE® TUBE 2.5 ml CAT Serum Separator Clot Activator 13x75 red cap-yellow ring, G-barcode label, PREMIUM	484513A	41128
CAT	Serum Sep Clot Activator	VACUETTE® TUBE 3.5 ml CAT Serum Separator Clot Activator 13x75 red cap-yellow ring, G-barcode label, PREMIUM	484514A	41128

VACUETTE® Tube Group	Additive	Product name - detailed product description	Item No.	GMDN
CAT	Serum Sep Clot Activator	VACUETTE® TUBE 8 ml CAT Serum Separator Clot Activator 16x100 red cap-yellow ring, G-barcode label, non-ridged	485502A	41128
CAT	Serum Sep Clot Activator	VACUETTE® TUBE 4 ml CAT Serum Separator Clot Activator 16x100 red cap-yellow ring, G-barcode label, non-ridged	485514A	41128
CAT	Serum Sep Clot Activator	VACUETTE® TUBE 5 ml CAT Serum Separator Clot Activator 13x100 white cap-yellow ring, KOH barcode label, non-ridged	486004A	41128
CAT	Serum Sep Clot Activator	VACUETTE® TUBE 5 ml CAT Serum Separator Clot Activator 13x100 red cap-yellow ring, KOH barcode label, non-ridged	486005A	41128
CAT	Serum Sep Clot Activator	VACUETTE® TUBE 5 ml CAT Serum Separator Clot Activator 13x100 royal blue cap-yellow ring, KOH barcode label, non-ridged	486006A	41128
CAT	Serum Sep Clot Activator	VACUETTE® TUBE 5 ml CAT Serum Separator Clot Activator 13x100 yellow cap-yellow ring, KOH barcode label, non-ridged	486007A	41128
CAT	Serum Sep Clot Activator	VACUETTE® TUBE 5 ml CAT Serum Separator Clot Activator 13x100 gold cap-gold ring, black KOH barcode label, non-ridged	486018A	41128
CAT	Serum Sep Clot Activator	VACUETTE® TUBE 5 ml CAT Serum Separator Clot Activator 13x100 pink cap-yellow ring, KOH barcode label, non-ridged	486019A	41128
CAT	Serum Sep Clot Activator	VACUETTE® TUBE 5 ml CAT Serum Separator Clot Activator 13x100 gold cap-gold ring, black G-barcode label, PREMIUM	486500A	41128
CAT	Serum Sep Clot Activator	VACUETTE® TUBE 5 ml CAT Serum Separator Clot Activator 13x100 red cap-yellow ring, G-barcode label, PREMIUM	486503A	41128
K2E	K2EDTA Sep	VACUETTE® TUBE 3.5 ml K2E K2EDTA Separator 13x75 lavender cap-yellow ring, PREMIUM	454235A	47587

VACUETTE® Tube Group	Additive	Product name - detailed product description	Item No.	GMDN
K2E	K2EDTA Sep	VACUETTE® TUBE 8 ml K2E K2EDTA Separator 16x100 white cap-yellow ring, non-ridged	455021A	47587
K2E	K2EDTA Sep	VACUETTE® TUBE 5 ml K2E K2EDTA Separator 13x100 white cap-yellow ring, non-ridged	456058A	47587
K2E	K2EDTA Sep	VACUETTE® TUBE 5 ml K2E K2EDTA Separator 13x100 white cap-yellow ring, PREMIUM	456211A	47587
LH	Lithium Heparin Sep	VACUETTE® TUBE 3.5 ml LH Lithium Heparin Separator 13x75 green cap-yellow ring, non-ridged	454008A	47587
LH	Lithium Heparin Sep	VACUETTE® TUBE 2.5 ml LH Lithium Heparin Separator 13x75 green cap-yellow ring, PREMIUM	454046A	47587
LH	Lithium Heparin Sep	VACUETTE® TUBE 3.5 ml LH Lithium Heparin Separator 13x75 green cap-yellow ring, PREMIUM	454083A	47587
LH	Lithium Heparin Sep	VACUETTE® TUBE 3 ml LH Lithium Heparin Separator 13x75 green cap-yellow ring, non-ridged	454247A	47587
LH	Lithium Heparin Sep	VACUETTE® TUBE 3.5 ml LH Lithium Heparin Separator 13x75 green cap-yellow ring, special label, non-ridged	454483A	47587
LH	Lithium Heparin Sep	VACUETTE® TUBE 3.5 ml LH Lithium Heparin Separator 13x75 mint green cap-yellow ring, transparent label, non-ridged	454489A	47587
LH	Lithium Heparin Sep	VACUETTE® TUBE 3 ml LH Lithium Heparin Separator 13x75 green cap-yellow ring, transparent label, non-ridged	454491A	47587
LH	Lithium Heparin Sep	VACUETTE® TUBE 3 ml LH Lithium Heparin Separator 13x75 mint green cap-yellow ring, transparent label, non-ridged	454493A	47587
LH	Lithium Heparin Sep	VACUETTE® TUBE 8 ml LH Lithium Heparin Separator 16x100 green cap-yellow ring, non-ridged	455083A	47587
LH	Lithium Heparin Sep	VACUETTE® TUBE 4 ml LH Lithium Heparin Separator 16x100 green cap-yellow ring, non-ridged	455229A	47587

VACUETTE® Tube Group	Additive	Product name - detailed product description	Item No.	GMDN
LH	Lithium Heparin Sep	VACUETTE® TUBE 5 ml LH Lithium Heparin Separator 13x100 green cap-yellow ring, PREMIUM	456083A	47587
LH	Lithium Heparin Sep	VACUETTE® TUBE 5 ml LH Lithium Heparin Separator 13x100 green cap-yellow ring, non-ridged	456087A	47587
LH	Lithium Heparin Sep	VACUETTE® TUBE 5 ml LH Lithium Heparin Separator 13x100 green cap-yellow ring, transparent label, non-ridged	456216A	47587
LH	Lithium Heparin Sep	VACUETTE® TUBE 3.5 ml LH Lithium Heparin Separator 13x100 green cap-yellow ring, non-ridged	456287A	47587
LH	Lithium Heparin Sep	VACUETTE® TUBE 5 ml LH Lithium Heparin Separator 13x100 mint green cap-yellow ring, transparent label, non-ridged	456305A	47587
LH	Lithium Heparin Sep	VACUETTE® TUBE 3.5 ml LH Lithium Heparin Separator 13x75 green cap-yellow ring, transparent label, PREMIUM	474083A	47587
LH	Lithium Heparin Sep	VACUETTE® TUBE 3.5 ml LH Lithium Heparin Separator 13x75 green cap-red ring, barcode label, non-ridged	484030A	47587
LH	Lithium Heparin Sep	VACUETTE® TUBE 3.5 ml LH Lithium Heparin Separator 13x75 green cap-yellow ring, barcode label, non-ridged	484031A	47587
LH	Lithium Heparin Sep	VACUETTE® TUBE 3.5 ml LH Lithium Heparin Separator 13x75 green cap-yellow ring, G-barcode label, PREMIUM	484523A	47587
LH	Lithium Heparin Sep	VACUETTE® TUBE 5 ml LH Lithium Heparin Separator 13x100 green cap-yellow ring, G-barcode label, non-ridged	486507A	47587