

## 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

Product / Product Group: VACUETTE® URINE CCM TUBES  
(for details please refer to page 2)

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

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

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, 08.08.2019



Signature:   
Georg Sambs  
Reg. Affairs Manager

PRODUCT GROUP	Product name - detailed product description	Item numbers	GMDN Code
VACUETTE® URINE CCM TUBES	VACUETTE® TUBE 4 ml Urine CCM 13x75 yellow cap-black ring, Round Base, non-ridged	454486	58151
VACUETTE® URINE CCM TUBES	VACUETTE® TUBE 10 ml Urine CCM 16x100 yellow cap-black ring, Round Base, non-ridged	455052	58151
VACUETTE® URINE CCM TUBES	VACUETTE® TUBE 9 ml Urine CCM 16x100 yellow cap-black ring, Conical Base, non-ridged	455243	58151
VACUETTE® URINE CCM TUBES	VACUETTE® TUBE 6 ml Urine CCM 13x100 yellow cap-black ring, Round Base, non-ridged	456284	58151
VACUETTE® URINE CCM TUBES	VACUETTE® TUBE 10 ml Urine CCM 16x100 yellow cap-black ring, Round Base, ISLAB barcode label, non-ridged	485052	58151
VACUETTE® URINE CCM TUBES	VACUETTE® TUBE 10 ml Urine CCM 16x100 yellow cap-black ring, Round Base, ISLAB barcode label M, non-ridged	485052M	58151
VACUETTE® URINE CCM TUBES	VACUETTE® TUBE 10 ml Urine CCM 16x100 yellow cap-black ring, barcode label, G-Code, Round Base, non-ridged	485511	58151
VACUETTE® URINE CCM TUBES	VACUETTE® TUBE 6 ml Urine CCM 13x100 yellow cap-black ring, Round Base, bi-barcode label, non-ridged	496510	58151