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greiner BIO-ONE

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):	58151

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, 09.07.2025

greiner QM bio-one

Signature: .....

Johann Sperneder
PRRC

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PRODUCT GROUP	Product name - detailed product description	Item numbers
VACUETTE® URINE CCM TUBES	VACUETTE® TUBE 4 ml Urine CCM 13x75 yellow cap-black ring, Round Base, non-ridged	454486
VACUETTE® URINE CCM TUBES	VACUETTE® TUBE 8 ml Urine CCM 16x100 yellow cap-black ring, Round Base, non-ridged	455041
VACUETTE® URINE CCM TUBES	VACUETTE® TUBE 10 ml Urine CCM 16x100 yellow cap-black ring, Round Base, non-ridged	455052
VACUETTE® URINE CCM TUBES	VACUETTE® TUBE 9 ml Urine CCM 16x100 yellow cap-black ring, Conical Base, non-ridged	455243
VACUETTE® URINE CCM TUBES	VACUETTE® TUBE 6 ml Urine CCM 13x100 yellow cap-black ring, Round Base, non-ridged	456284
VACUETTE® URINE CCM TUBES	VACUETTE® TUBE 4 ml Urine CCM 13x75 yellow cap-black ring, G-barcode label, Round base, non-ridged	484532
VACUETTE® URINE CCM TUBES	VACUETTE® TUBE 10 ml Urine CCM 16x100 yellow cap-black ring, Round Base, ISLAB barcode label M, non-ridged	485052M
VACUETTE® URINE CCM TUBES	VACUETTE® TUBE 10 ml Urine CCM 16x100 yellow cap-black ring, G-barcode label, Round Base, non-ridged	485511
VACUETTE® URINE CCM TUBES	VACUETTE® TUBE 6 ml Urine CCM 13x100 yellow cap-black ring, Round Base, G-bi-barcode label, non-ridged	496510