



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 Str. 32
4550 Kremsmünster
AUSTRIA

Production Greiner Bio-One GmbH
Location: Bad Haller Str. 32
4550 Kremsmünster
AUSTRIA

Product/ VACUETTE® URINE TUBES
Product Group: (for details please refer to pages 2-4)
Classification: Other device (all devices except Annex II and except self-testing
devices)

GMDN Codes (for details please refer to pages 2-4)

We herewith declare under our sole responsibility that the above mentioned products meet the provisions of the following EC Council Directives and 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, 09.03.2018



Signature:



Georg Sambs
Reg. Affairs Manager

PRODUCT GROUP	Product name - detailed product description	Item numbers	GMDN Code
VACUETTE® URINE TUBES	VACUETTE® TUBE 4 ml Urine Culture 13x75 yellow cap-black ring, Round Base, non-ridged	454239	58150
VACUETTE® URINE TUBES	VACUETTE® TUBE 4 ml Z Urine No Additive 13x75 black cap-black ring, Round Base, transparent label, non-ridged	454419	58158
VACUETTE® URINE TUBES	VACUETTE® TUBE 4 ml Urine Stabilur 13x75 yellow cap-red ring, Round Base, non- ridged	454463	58151
VACUETTE® URINE TUBES	VACUETTE® TUBE 10 ml Urine Culture 16x100 yellow cap-black ring, Round Base, non-ridged	455003	58150
VACUETTE® URINE TUBES	VACUETTE® TUBE 10 ml Z Urine No Additive 16x100 yellow cap-yellow ring, Round Base, non-ridged	455007	58158
VACUETTE® URINE TUBES	VACUETTE® TUBE 9 ml Z Urine No Additive 16x100 yellow cap-yellow ring, Conical Base, non-ridged	455028	58158
VACUETTE® URINE TUBES	VACUETTE® TUBE 9 ml Urine Culture 16x100 yellow cap-black ring, Conical Base, non-ridged	455029	58150
VACUETTE® URINE TUBES	VACUETTE® TUBE 10 ml Urine Stabilur 16x100 yellow cap-red ring, Round Base, non- ridged	455048	58151
VACUETTE® URINE TUBES	VACUETTE® TUBE 9 ml Urine Stabilur 16x100 yellow cap-red ring, Conical Base, non-ridged	455049	58151
VACUETTE® URINE TUBES	VACUETTE® TUBE 9 ml Z Urine No Additive 16x100 white cap-black ring, Conical Base, non-ridged	455209	58158
VACUETTE® URINE TUBES	VACUETTE® TUBE 10 ml Z Urine No Additive 16x100 yellow cap-red ring, Round Base, non- ridged	455210	58158
VACUETTE® URINE TUBES	VACUETTE® TUBE 8 ml Z Urine No Additive 16x100 yellow cap-black ring, Round Base, non-ridged	455225	58158



PRODUCT GROUP	Product name - detailed product description	Item numbers	GMDN Code
VACUETTE® URINE TUBES	VACUETTE® TUBE 7 ml Z Urine No Additive 16x100 yellow cap-yellow ring, Round Base, non-ridged	455227	58158
VACUETTE® URINE TUBES	VACUETTE® TUBE 6 ml Z Urine No Additive 13x100 yellow cap-yellow ring, Round Base, PREMIUM	456007	58158
VACUETTE® URINE TUBES	VACUETTE® TUBE 6 ml Urine Culture 13x100 yellow cap-black ring, Round Base, ridged	456009	58150
VACUETTE® URINE TUBES	VACUETTE® TUBE 6 ml Z Urine No Additive 13x100 yellow cap-yellow ring, Round Base, non-ridged	456065	58158
VACUETTE® URINE TUBES	VACUETTE® TUBE 6 ml Z Urine No Additive 13x100 yellow cap-yellow ring, Round Base, PREMIUM	456707	58158
VACUETTE® URINE TUBES	VACUETTE® TUBE 6 ml Z Urine No Additive 13x100 yellow cap-yellow ring, transparent label, Round Base, PREMIUM	476081	58158
VACUETTE® URINE TUBES	VACUETTE® TUBE 9 ml Z Urine No Additive 16x100 white cap-red ring, barcode label, Round Base, non-ridged	485001	58158
VACUETTE® URINE TUBES	VACUETTE® TUBE 9 ml Z Urine No Additive 16x100 red cap-red ring, red barcode label, Round Base, non-ridged	485002	58158
VACUETTE® URINE TUBES	VACUETTE® TUBE 9 ml Z Urine No Additive 16x100 royal blue cap-red ring, blue barcode label, Round Base, non-ridged	485008	58158
VACUETTE® URINE TUBES	VACUETTE® TUBE 9 ml Z Urine No Additive 16x100 yellow cap-yellow ring, barcode label, Conical Base, non-ridged	485022	58158
VACUETTE® URINE TUBES	VACUETTE® TUBE 9 ml Z Urine No Additive 16x100 yellow cap-red ring, barcode label, Conical Base, non-ridged	485028	58158



PRODUCT GROUP	Product name - detailed product description	Item numbers	GMDN Code
VACUETTE® URINE TUBES	VACUETTE® TUBE 9.5 ml Urine Stabilur 16x100 yellow cap-red ring, barcode label, Round base, non-ridged	485048	58151
VACUETTE® URINE TUBES	VACUETTE® TUBE 9 ml Z Urine No Additive 16x100 yellow cap-yellow ring, barcode label, G-Code, Conical Base, non-ridged	485507	58158
VACUETTE® URINE TUBES	VACUETTE® TUBE 9 ml Z Urine No Additive 16x100 yellow cap-yellow ring, bi-barcode label, Conical Base, non-ridged	495028	58158