

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 TUBES (No Additive)
(for details please refer to page 2-3)

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

GMDN Code(s): 58158


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, 22.03.2021



Signature: 
Georg Sambs
Quality Manager GBO AT

PRODUCT GROUP	Product name - detailed product description	Item numbers
VACUETTE® URINE No Additive TUBES	VACUETTE® TUBE 3 ml Z Urine No Additive 13x75 yellow cap-yellow ring, Round Base, PREMIUM	454141
VACUETTE® URINE No Additive TUBES	VACUETTE® TUBE 4 ml Z Urine No Additive 13x75 black cap-black ring, Round Base, transparent label, non-ridged	454419
VACUETTE® URINE No Additive TUBES	VACUETTE® TUBE 10 ml Z Urine No Additive 16x100 yellow cap-yellow ring, Round Base, non-ridged	455007
VACUETTE® URINE No Additive TUBES	VACUETTE® TUBE 9 ml Z Urine No Additive 16x100 yellow cap-yellow ring, Conical Base, non-ridged	455028
VACUETTE® URINE No Additive TUBES	VACUETTE® TUBE 9 ml Z Urine No Additive 16x100 white cap-black ring, Conical Base, non-ridged	455209
VACUETTE® URINE No Additive TUBES	VACUETTE® TUBE 10 ml Z Urine No Additive 16x100 yellow cap-red ring, Round Base, non-ridged	455210
VACUETTE® URINE No Additive TUBES	VACUETTE® TUBE 8 ml Z Urine No Additive 16x100 yellow cap-black ring, Round Base, non-ridged	455225
VACUETTE® URINE No Additive TUBES	VACUETTE® TUBE 7 ml Z Urine No Additive 16x100 yellow cap-yellow ring, Round Base, non-ridged	455227
VACUETTE® URINE No Additive TUBES	VACUETTE® TUBE 6 ml Z Urine No Additive 13x100 yellow cap-yellow ring, Round Base, PREMIUM	456007
VACUETTE® URINE No Additive TUBES	VACUETTE® TUBE 6 ml Z Urine No Additive 13x100 yellow cap-yellow ring, Round Base, non-ridged	456065
VACUETTE® URINE No Additive TUBES	VACUETTE® TUBE 6 ml Z Urine No Additive 13x100 yellow cap-yellow ring, Round Base, PREMIUM	456707
VACUETTE® URINE No Additive TUBES	VACUETTE® TUBE 6 ml Z Urine No Additive 13x100 yellow cap-yellow ring, transparent label, Round Base, PREMIUM	476081
VACUETTE® URINE No Additive TUBES	VACUETTE® TUBE 9 ml Z Urine No Additive 16x100 white cap-red ring, KOH barcode label, Round Base, non-ridged	485001
VACUETTE® URINE No Additive TUBES	VACUETTE® TUBE 9 ml Z Urine No Additive 16x100 red cap-red ring, red KOH barcode label, Round Base, non-ridged	485002
VACUETTE® URINE No Additive TUBES	VACUETTE® TUBE 10 ml Z Urine No Additive 16x100 yellow cap-yellow ring, Round Base, ISLAB barcode label, non-ridged	485007

PRODUCT GROUP	Product name - detailed product description	Item numbers
VACUETTE® URINE No Additive TUBES	VACUETTE® TUBE 10 ml Z Urine No Additive 16x100 yellow cap-yellow ring, Round Base, ISLAB barcode label M, non- ridged	485007M
VACUETTE® URINE No Additive TUBES	VACUETTE® TUBE 9 ml Z Urine No Additive 16x100 royal blue cap-red ring, blue KOH barcode label, Round Base, non- ridged	485008
VACUETTE® URINE No Additive TUBES	VACUETTE® TUBE 9 ml Z Urine No Additive 16x100 yellow cap-red ring, KOH barcode label, Conical Base, non-ridged	485028
VACUETTE® URINE No Additive TUBES	VACUETTE® TUBE 9 ml Z Urine No Additive 16x100 yellow cap-yellow ring, GeT barcode label, Conical Base, non- ridged	485507
VACUETTE® URINE No Additive TUBES	VACUETTE® TUBE 10 ml Z Urine No Additive 16x100 yellow cap-yellow ring, Round Base, GeT barcode label, non- ridged	485510
VACUETTE® URINE No Additive TUBES	VACUETTE® TUBE 10 ml Z Urine No Additive 16x100 yellow cap-yellow ring, Round Base, GeT Bi-Barcode label, non- ridged	495007
VACUETTE® URINE No Additive TUBES	VACUETTE® TUBE 9 ml Z Urine No Additive 16x100 yellow cap-yellow ring, GeT bi-barcode label, Conical Base, non- ridged	495028