

ES Prohlášení o shodě

Shoda se SMĚRNICÍ 98/79/ES EVROPSKÉHO PARLAMENTU A
RADY ze dne 27. října 1998 o diagnostických zdravotnických prostředcích in vitro

Výrobce:	Greiner Bio-One GmbH Bad Haller Strasse 32 4550 Kremsmünster Rakousko
Místo výroby:	Greiner Bio-One GmbH Bad Haller Strasse 32 4550 Kremsmünster Rakousko
Výrobek / Výrobová skup.:	VACUETTE® URINE TUBES (No Additive) (podrobné informace najdete na str. 2 - 3)
Klasifikace:	Jiný prostředek (všechny prostředky kromě Přílohy II a kromě sebetestovacích prostředků)
GMDN kód/y:	58158

Tímto prohlašujeme výhradně na vlastní odpovědnost, že výše uvedené výrobky splňují ustanovení výše uvedené Směrnice ES Rady a příslušné normy. Veškerá podpůrná dokumentace je uchovávána výrobcem v jeho prostorách.

Postup posouzení shody podle Přílohy III směrnice 98/79/ES Evropského parlamentu a Rady o diagnostických zdravotnických prostředcích in vitro.

Normy:

Viz seznam příslušných (harmonizovaných) norem v technické dokumentaci.

Kremsmünster, 14.07.2023



Podpis: *nečitelné*
Georg Sambs
Ředitel kvality GBO AT

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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.

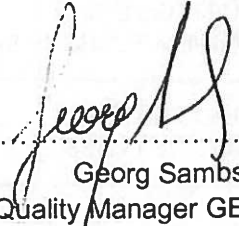
Standards:

Refer to the List of applicable (harmonized) standards in the Technical Documentation.

Kremsmünster, 14.07.2023



Signature:


Georg Sams
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, G-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, G-barcode label, non-ridged	485510
VACUETTE® URINE No Additive TUBES	VACUETTE® TUBE 7 ml Z Urine No Additive 16x100 yellow cap-yellow ring, Round Base, G-barcode label, non-ridged	485523
VACUETTE® URINE No Additive TUBES	VACUETTE® TUBE 6 ml Z Urine No Additive 13x100 yellow cap-yellow ring, Round Base, G-barcode label, PREMIUM	486027
VACUETTE® URINE No Additive TUBES	VACUETTE® TUBE 10 ml Z Urine No Additive 16x100 yellow cap-yellow ring, Round Base, G-Bi-Barcode label, non-ridged	495007
VACUETTE® URINE No Additive TUBES	VACUETTE® TUBE 9 ml Z Urine No Additive 16x100 yellow cap-yellow ring, G-bi-barcode label, Conical Base, non-ridged	495028

<p>1. The first...</p>	<p>The first...</p>	<p>...</p>
<p>2. The second...</p>	<p>The second...</p>	<p>...</p>
<p>3. The third...</p>	<p>The third...</p>	<p>...</p>
<p>4. The fourth...</p>	<p>The fourth...</p>	<p>...</p>
<p>5. The fifth...</p>	<p>The fifth...</p>	<p>...</p>
<p>6. The sixth...</p>	<p>The sixth...</p>	<p>...</p>