CE

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<br>Bad Haller Straße 32<br>4550 Kremsmünster<br>Austria |
| Production Location: | Greiner Bio-One GmbH<br>Bad Haller Straße 32<br>4550 Kremsmünster<br>Austria |
| Product / Product Group: | VACUETTE® URINE TUBES (No Additive)<br>(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, 09.07.2025

greiner QM bio-one

Signature: .....

Johann Sperneder
PRRC

CE

greiner BIO-ONE

| 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, non-ridged | 454142 |
| 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 black cap-black ring, round base, non-ridged | 455002 |
| 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 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 4 ml Z Urine No Additive 13x75 yellow cap-yellow ring, Round Base, G-barcode label, PREMIUM | 484533 |
| 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 |

CE

greiner BIO-ONE

| PRODUCT GROUP | Product name - detailed product description | Item numbers |
|---|---|---|
| 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 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 |