



## 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 Greiner Bio-One GmbH Greiner Bio-One Hungary Kft.  
Location: Bad Haller Straße 32 Fertősor 7  
4550 Kremsmünster 9200 Mosonmagyaróvár  
Austria Hungary

Product / Urine Beaker (sterile)  
Product Group: (for details please refer to page 2)

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

GMDN Code(s): 47775

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, 22.07.2024



Signature: .....

Georg Sambs  
Quality Manager GBO AT



| PRODUCT GROUP          | Product name - detailed product description                                            | Item numbers |
|------------------------|----------------------------------------------------------------------------------------|--------------|
| Urine Beaker (sterile) | Urine Beaker with integrated Transfer Device 100 ml, yellow lid single-packed, sterile | 724310       |
| Urine Beaker (sterile) | Urine Beaker with integrated Transfer Device 100 ml, yellow lid 5 pcs./bag, sterile    | 724311       |
| Urine Beaker (sterile) | Urine Cup with integrated Transfer Device 100 ml bulk-packed, sterile                  | 724321       |
| Urine Beaker (sterile) | Urine Cup with integrated Transfer Device 100 ml 10 pcs./bag, sterile                  | 724325       |