



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 Hungary Chirana T. Injecta, a.s.
Location: Kft. Fertősor 7 9200 Nám. Dr. Schweitzera 194
Mosonmagyaróvár 916 01 Stará Turá
Hungary Slovakia

Product/ Urine Transfer Device
Product Group: (for details please refer to page 2)

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

GMDN Codes (for details please refer to page 2)

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
Urine Transfer Device	Urine Transfer Device, short 50 pcs. per bag	450251	58156
Urine Transfer Device	Urine Transfer Device, long	450252	58156
Urine Transfer Device	Urine Transfer Device, short single-packed, sterile	450253	58157
Urine Transfer Device	Urine Transfer Device, short 600 pcs. in total	450751	58156
Urine Transfer Device	Urine Transfer Device short Russia 50 pcs. per bag	450251RU	58156