CE

greiner BIO-ONE

EU Declaration of Conformity

to REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on in vitro diagnostic medical devices

Manufacturer:	Greiner Bio-One GmbH Bad Haller Straße 32 4550 Kremsmünster Austria	SRN: AT-MF-000024608
Production Location:	Greiner Bio-One Hungary Kft. Fertösor 7 9200 Mosonmagyaróvár Hungary	
Product / Product Group:	Urine Transfer Device (for details please refer to page 2)	

BASIC-UDI-DI (GMN): 912001757G00000639X

Classification: Class A according to Regulation (EU) 2017/746 of the european parliament and of the council of 5 April 2017 on in vitro diagnostic medical devices, Annex VIII Classification Rules - Rule 5

GMDN Code(s): 58157

We herewith declare under our sole responsibility that the products specified above meet the provisions of the above-mentioned Regulation. All supporting documentation is retained under the premises of the manufacturer.

Conformity Assessment procedure acc. to Annex IV of the Regulation (EU) 2017/746.

Standards / common specifications:
Refer to the list of applicable (harmonized) standards and common specifications in the Technical Documentation.

Kremsmünster, 24.03.2023

greiner QM bio-one

Georg Sambs
Quality Manager
Greiner Bio-One Austria

CE

greiner BIO-ONE

PRODUCT GROUP	Product name - detailed product description	Item numbers
Urine Transfer Device (non-sterile)	Urine Transfer Device, short 50 pcs. per bag	450251
Urine Transfer Device (non-sterile)	Urine Transfer Device, long	450252
Urine Transfer Device (non-sterile)	Urine Transfer Device, short single-packed, non-sterile 400 pcs. in total	450264
Urine Transfer Device (non-sterile)	Urine Transfer Device, short 600 pcs. in total	450751