

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 SRN: AT-MF-000024608
Bad Haller Straße 32
4550 Kremsmünster
Austria

Production Greiner Bio-One Hungary Kft.
Location: Fertőszor 7
9200 Mosonmagyaróvár
Hungary

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

Intended Use: VACUETTE® Urine Tubes, Urine Beakers/Cups, and Urine Transfer Devices are
used together as a system for the collection, transport, processing and testing of
urine in the clinical laboratory.
Urine Transfer Devices enable a clean transfer of the urine sample collected in a
container directly into VACUETTE® Urine Tubes.

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, 25.11.2025


Daniel Stocker
PRRC
Person Responsible for Regulatory Compliance

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