

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: N/A
Bad Haller Straße 32
4550 Kremsmünster
Austria

Production Greiner Bio-One GmbH
Location: Bad Haller Straße 32
4550 Kremsmünster
Austria

Product / MiniCollect® CAT Serum (Sep) TUBE
Product Group: (for details please refer to page 2)

BASIC-UDI-DI (GMN): MiniCollect® CAT Serum Sep TUBE: 912001757G00000469X
MiniCollect® CAT Serum TUBE: 912001757G00000459V

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): MiniCollect® CAT Serum Sep TUBE: 58138
MiniCollect® CAT Serum TUBE: 58140

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, 20.05.2022




Georg Sambs
Quality Manager
Greiner Bio-One Austria

PRODUCT GROUP	Product name - detailed product description	Item numbers
MiniCollect® CAT Serum Sep TUBE	MiniCollect® TUBE 0.5/0.8 ml CAT Serum Sep Clot Activator gold cap	450533
MiniCollect® CAT Serum TUBE	MiniCollect® TUBE 0.5 / 1 ml CAT Serum Clot Activator red cap	450534
MiniCollect® CAT Serum Sep TUBE	MiniCollect® Complete 0.5 / 0.8 ml CAT Serum Separator Clot Activator gold cap, pre-assembled with Carrier Tube 13x75	450548
MiniCollect® CAT Serum TUBE	MiniCollect® Complete 0.5 / 1 ml CAT Serum Clot Activator red cap, pre-assembled with Carrier Tube 13x75	450549
MiniCollect® CAT Serum Sep TUBE	MiniCollect® Complete 0.5 / 0.8 ml CAT Serum Separator Clot Activator gold cap, paper label, pre-assembled with Carrier Tube 13x75	450568
MiniCollect® CAT Serum TUBE	MiniCollect® Complete 0.5 / 1 ml CAT Serum Clot Activator red cap, paper label, pre-assembled with Carrier Tube 13x75	450569
MiniCollect® CAT Serum Sep TUBE	MiniCollect® Complete 0.5 / 0.8 ml CAT Serum Separator Clot Activator gold cap, ISLAB barcode label, pre-assembled with Carrier Tube 13x75	480148
MiniCollect® CAT Serum TUBE	MiniCollect® Complete 0.5 / 1 ml CAT Serum Clot Activator red cap, G-barcode label, pre-assembled with Carrier Tube 13x75	480548
MiniCollect® CAT Serum Sep TUBE	MiniCollect® Complete 0.5 / 0.8 ml CAT Serum Separator Clot Activator gold cap, G-barcode label, pre-assembled with Carrier Tube 13x75	480568