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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 GmbH Bad Haller Straße 32 4550 Kremsmünster Austria	
Product / Product Group:	MiniCollect® CAT Serum (Sep) TUBE (for details please refer to page 2)	
Intended Use:	To collect, transport, separate and process capillary blood for testing serum in the clinical laboratory.	
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 MiniCollect® CAT Serum TUBE:	58138 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, 25.11.2025

greiner QM bio-one

Daniel Stocker
PRRC
Person Responsible for Regulatory Compliance

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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