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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® FX Sodium Fluoride / Potassium Oxalate TUBE (for details please refer to page 2)	
BASIC-UDI-DI (GMN):	912001757G0000056A2	
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):	58153	

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 IVof 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

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Georg Sambs
Quality Manager
Greiner Bio-One Austria

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PRODUCT GROUP	Product name - detailed product description	Item numbers
MiniCollect® FX Sodium Fluoride / Potassium Oxalate TUBE	MiniCollect® TUBE 0.25 ml FX Sodium Fluoride / Potassium Oxalate grey cap	450540
MiniCollect® FX Sodium Fluoride / Potassium Oxalate TUBE	MiniCollect® TUBE 0.5 ml FX Sodium Fluoride / Potassium Oxalate grey cap	450541
MiniCollect® FX Sodium Fluoride / Potassium Oxalate TUBE	MiniCollect® Complete 0.25 ml FX Sodium Fluoride / Potassium Oxalate grey cap, pre-assembled with Carrier Tube 13x75	450552
MiniCollect® FX Sodium Fluoride / Potassium Oxalate TUBE	MiniCollect® Complete 0.25 ml FX Sodium Fluoride / Potassium Oxalate grey cap, paper label, pre-assembled with Carrier Tube 13x75	450562
MiniCollect® FX Sodium Fluoride / Potassium Oxalate TUBE	MiniCollect® Complete 0.25 ml FX Sodium Fluoride / Potassium Oxalate grey cap, G-barcode label, pre-assembled with Carrier Tube 13x75	480549