

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® LH Lithium Heparin (Sep) TUBE
Product Group: (for details please refer to page 2)

BASIC-UDI-DI (GMN): MiniCollect® LH Lithium Heparin Sep TUBE 912001757G0000048A3
MiniCollect® LH Lithium Heparin TUBE: 912001757G00000479Z

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® LH Lithium Heparin Sep TUBE: 58145
MiniCollect® LH Lithium Heparin TUBE: 61388

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® LH Lithium Heparin Sep TUBE	MiniCollect® TUBE 0.8 ml LH Lithium Heparin Separator light-green cap	450535
MiniCollect® LH Lithium Heparin TUBE	MiniCollect® TUBE 0.5 ml LH Lithium Heparin green cap	450536
MiniCollect® LH Lithium Heparin TUBE	MiniCollect® TUBE 1 ml LH Lithium Heparin green cap	450537
MiniCollect® LH Lithium Heparin Sep TUBE	MiniCollect® Complete 0.8 ml LH Lithium Heparin Separator light-green cap, pre-assembled with Carrier Tube 13x75	450550
MiniCollect® LH Lithium Heparin TUBE	MiniCollect® Complete 1 ml LH Lithium Heparin green cap, pre-assembled with Carrier Tube 13x75	450551
MiniCollect® LH Lithium Heparin Sep TUBE	MiniCollect® Complete 0.8 ml LH Lithium Heparin Separator light-green cap, paper label, pre-assembled with Carrier Tube 13x75	450560
MiniCollect® LH Lithium Heparin TUBE	MiniCollect® Complete 1 ml LH Lithium Heparin green cap, paper label, pre-assembled with Carrier Tube 13x75	450651
MiniCollect® LH Lithium Heparin TUBE	MiniCollect® TUBE 0.5 ml LH Lithium Heparin green cap, G-barcode label	480536
MiniCollect® LH Lithium Heparin TUBE	MiniCollect® Complete 0.5 ml LH Lithium Heparin green cap, G-barcode label, pre-assembled with Carrier Tube 13x75	480550
MiniCollect® LH Lithium Heparin Sep TUBE	MiniCollect® Complete 0.8 ml LH Lithium Heparin Separator light-green cap, pre-assembled with Carrier Tube 13x75, barcode label	480650