

## EC Declaration of Conformity

Conformity to DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 1998 on in vitro diagnostic medical devices

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

Production Location: SC Sanguis Counting  
Kontrollblutherstellungs- und Vertriebs GmbH  
Im Löchelchen 11  
51588 Nümbrecht  
Germany

Product / Product Group: MiniCollect® Capillary  
(for details please refer to page 2)

Classification: Other device (all devices except Annex II and except self-testing devices)

GMDN Code(s): (for details please refer to page 2)

We herewith declare under our sole responsibility that the above mentioned products meet the provisions of the above EC Council Directive and the applicable standards. All supporting documentations are retained under the premises of the manufacturer.

Conformity Assessment procedure acc. to Annex III of the Directive 98/79/EC of the European Parliament and of the Council on in vitro diagnostic medical devices.

Standards:  
Refer to the List of applicable (harmonized) standards in the Technical Documentation.

Kremsmünster, 06.08.2021



Signature:   
Georg Sambs  
Quality Manager GBO AT



<b>PRODUCT GROUP</b>	<b>Product name - detailed product description</b>	<b>Item numbers</b>	<b>GMDN Code</b>
MiniCollect® Capillary Serum	MiniCollect® Capillary for Serum, 250 µL	450430	58152
MiniCollect® Capillary Serum	MiniCollect® Capillary for Serum, 80 µL	450431	58152
MiniCollect® Capillary EDTA	MiniCollect® Capillary for EDTA, 250 µL	450433	58154
MiniCollect® Capillary EDTA	MiniCollect® Capillary for EDTA, 80 µL	450434	58154
MiniCollect® Capillary Heparin	MiniCollect® Capillary for Heparin, 250 µL	450435	58155
MiniCollect® Capillary Heparin	MiniCollect® Capillary for Heparin, 80 µL	450436	58155