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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:	Greiner Bio-One GmbH Bad Haller Straße 32 4550 Kremsmünster Austria	Greiner Bio-One North America Inc. 4238 Capital Drive Monroe NC 28110 United States of America
Product / Product Group:	Plastic Cannula HOLDEX® (for details please refer to page 2)	
Classification:	Other device (all devices except Annex II and except self-testing devices)	
GMDN Code(s):	60579	

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, 08.04.2021

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Signature: .....
Georg Sambs
Quality Manager GBO AT

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PRODUCT GROUP	Product name - detailed product description	Item numbers
Plastic Cannula HOLDEX®	Plastic Cannula HOLDEX® single-packed, sterile	450216
Plastic Cannula HOLDEX®	Plastic Cannula HOLDEX® Haemonetics single-packed, sterile	450223
Plastic Cannula HOLDEX®	VACUETTE® Sample Transfer Unit single-packed, sterile	450218