CE 0123

greiner BIO-ONE

EC Declaration of Conformity

Conformity to COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning 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
Product / Product Group:	HOLDEX® Single Use Holder (for details please refer to page 2)
Classification:	Class Is, according to COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices Annex IX, III Classification, 1.1 rule 1
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 V and Annex VII of the Council Directive 93/42/EEC concerning medical devices

TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 München
G2S 029670 0034 Rev. 00, valid until 26 May 2024

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

Kremsmünster, 13.09.2019

greiner QM bio-one

Signature: .....

Georg Sambs
Reg. Affairs Manager

CE 0123

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PRODUCT GROUP	Product name - detailed product description	Item numbers
HOLDEX® Single Use Holder	HOLDEX® Single-Use Holder PP single-packed, sterile, not made with natural rubber latex	450241
HOLDEX® Single Use Holder	HOLDEX® Single-Use Holder PP single-packed, sterile, not made with natural rubber latex, Japan	450249JP
HOLDEX® Single Use Holder	HOLDEX® Single-Use Holder PP single-packed, sterile	450263