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<br>Bad Haller Str. 32<br>4550 Kremsmünster<br>AUSTRIA |
| Production Location: | Greiner Bio-One GmbH<br>Bad Haller Str. 32<br>4550 Kremsmünster<br>AUSTRIA |
| Product/ Product Group: | HOLDEX® Single Use Holder (VACUETTE® SAFELINK)<br>(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 Codes | 60579 |

We herewith declare under our sole responsibility that the above mentioned products meet the provisions of the following EC Council Directives and 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 16 12 29670 028, valid until 23 January 2022

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

Kremsmünster, 07.11.2018

greiner QM bio-one

Signature: .....

Georg Sambs
Reg. Affairs Manager

| PRODUCT GROUP | Product name - detailed product description | Item numbers |
|---|---|---|
| HOLDEX® Single Use Holder | VACUETTE® SAFELINK<br>Holder with male luer lock<br>single-packed, not made with natural rubber latex | 450210 |