

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: Asahi Polyslider Company Ltd. HTL-Strefa S.A.
860-2 Misaki Maniwa ul. Adamówek 7
Okayama 719-3226 95-035 Ozorków
Japan Poland

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

Classification: Class IIa, according to COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices, Annex IX, III. Classification, 2.2, rule 6 without application of exceptions

GMDN Code(s): 61578

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 II and Annex VII of the Council Directive 93/42/EEC concerning medical devices


TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 München
G1 029670 0032 Rev. 00, valid until 23 October 2023

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

Kremsmünster, 22.03.2021



Signature:


Georg Sambs
Quality Manager GBO AT

| PRODUCT GROUP | Product name - detailed product description | Item numbers | Production Location |
|-----------------------------|---|--------------|---------------------|
| MiniCollect® Safety Lancets | MiniCollect® Safety Lancet penetration depth 1.00 mm pink, for capillary blood collection, sterile with blade | 450427 | 1 |
| MiniCollect® Safety Lancets | MiniCollect® Safety Lancet penetration depth 1.50 mm green, for capillary blood collection, sterile with blade | 450428 | 1 |
| MiniCollect® Safety Lancets | MiniCollect® Safety Lancet penetration depth 2.00 mm blue, for capillary blood collection, sterile with blade | 450429 | 1 |
| MiniCollect® Safety Lancets | MiniCollect® Safety Lancet 28G, penetration depth 1.25 mm lavender, for capillary blood collection, sterile with needle | 450438 | 1 |
| MiniCollect® Safety Lancets | MiniCollect® Safety Lancet 23G, penetration depth 2.25 mm orange, for capillary blood collection, sterile with needle | 450439 | 1 |
| MiniCollect® Safety Lancets | MiniCollect® Lancelino Safety Lancet 30G penetration depth 1.20 mm light-green, sterile, for capillary blood collection with needle | 450520 | 2 |
| MiniCollect® Safety Lancets | MiniCollect® Lancelino Safety Lancet 25G penetration depth 1,50 mm lavender, sterile, for capillary blood collection with needle | 450521 | 2 |
| MiniCollect® Safety Lancets | MiniCollect® Lancelino Safety Lancet 21G penetration depth 1.80 mm blue, sterile, for capillary blood collection with needle | 450522 | 2 |
| MiniCollect® Safety Lancets | MiniCollect® Lancelino Safety Lancet 21G penetration depth 2.40 mm green, sterile, for capillary blood collection with needle | 450523 | 2 |
| MiniCollect® Safety Lancets | MiniCollect® Lancelino Safety Lancet penetration depth 2.00 mm yellow, sterile, for capillary blood collection with blade, width 0.8 mm | 450524 | 2 |

¹ Asahi Polyslider Company Ltd.

² HTL-Strefa S.A.