



## EC Declaration of Conformity

Conformity to COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices

Manufacturer/EC-Rep.:

Greiner Bio-One GmbH

Adress:

Bad Haller Str.32

4550 Kremsmünster,

**AUSTRIA** 

Production

Asahi Polyslider Company, Limited,

Location:

860-2 Misaki Maniwa, Okayama 719-

3226 Japan

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** Codes

37466

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 and the notified body.

Conformity Assessment procedure acc. to: Annex II of the Council Directive 93/42/EEC concerning medical devices

Notified Body:

TÜV Product Service GmbH

Certificate No.:

G1131029670026, valid until 23 Oct 2018

Standards:

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

Kremsmünster, 26.11.2013

Signature

Reg. Affairs Manager





PRODUCT GROUP	Product name - detailed product description	Item numbers
MiniCollect® Safety Lancets	MiniCollect® Safety Lancets, Depth 1.00 mm, Colour pink, for capillary blood collection 10 boxes of 200 pcs., 2000 pcs. in total	450427
MiniCollect® Safety Lancets	MiniCollect® Safety Lancets, Depth 1.50 mm, Colour green, for capillary blood collection 10 boxes of 200 pcs., 2000 pcs. in total	450428
MiniCollect® Safety Lancets	MiniCollect® Safety Lancets, Depth 2.00 mm, Colour blue, for capillary blood collection 10 boxes of 200 pcs., 2000 pcs. in total	450429
MiniCollect® Safety Lancets	MiniCollect® Safety Lancets, Depth 1.25 mm, Colour purple, for capillary blood collection 10 boxes of 200 pcs., 2000 pcs. in total	450438
MiniCollect® Safety Lancets	MiniCollect® Safety Lancets, Depth 2.25 mm, Colour orange, for capillary blood collection 10 boxes of 200 pcs., 2000 pcs. in total	450439