

**EC Declaration of Conformity according to
MDD 93/42/EEC**

Product Description: **SurgiLance™ Safety Lancet**

Product Designation: **Lancing Devices, Blood**

UMDNS- Code: **16380**

Model No's: **SLN100, SLN170, SLN200, SLN240, SLN300,
SLN100S, SLN170S, SLN200S, SLN240S, SLN300S,
SLN103, SLN173, SLN203, SLN243, SLN303,
SLB200, SLB250, SLB200S, SLB250S, SLB203, SLB253**

We herewith declare that the products listed above are in compliance with the requirements set out in the Council Directive on the harmonization of the Laws of the Member States concerning Medical Device Directive 93/42/EEC.

Conformity Assessment Procedure: **Annex II without section 4 (MDD 93/42/EEC)**

Classification of the Product: **Class Ila Rule: 6 (MDD 93/42/EEC Annex IX)**

Manufacturer : **MediPurpose Pte. Ltd.**

Address : **10 Anson Road
#12-08 International Plaza, Singapore 079903**

EU Authorized: **Obelis S. A.**
Representative: **Bd. Général Wahis, 53
1030 Brussels,
Belgium**

This declaration is supported by EC quality assurance statement (Annex II without section 4), demonstrated by compliance to certificate number HD 60146306 0001 (Issued 10 February 2020/Exp: 26 May 2024), issued by Notified Body TÜV Rheinland LGA Products GmbH (0197).

This Declaration of conformity is valid in connection with the release of document for the respective batch of produced devices.

This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration and is only valid in connection with a batch specific Certificate of Compliance for all products concerned bearing the CE mark.



Patrick Yi, CEO

06 April 2020

Date