

EC Certificate
Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60146306 0001

Report No.: 12022723 010

Manufacturer: MediPurpose Pte. Ltd.
10 Anson Road
#12-08 International Plaza
Singapore 079903
Singapore

Products: Safety Lancets and Safety Scalpels
Replaces Approval, Registration No.:60128770 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2020-02-10

Date: 2020-02-10



Notified Body


Takashi Matsuda

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

**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



GIMA

SURGILANCE SAFETY NEEDLE G23 - automatic lancets

Code: 24514
Category: Lancets
Unit of sale: box of 100 pcs.
Minimum order: 1
Type: Medical device
Class: II A
NSIS: 16427
CND: V9009
EAN13: 8023279245141



Description: Multi purpose capillary blood sampling devices for all testing requirements. The one-step safety lancet is easier to use, no arming is required, and safer, once lancet is used it is rendered inoperable. High-speed delivery and penetration method minimizes patient pain and operator error.

Latex-free, hypo-allergenic, disposable, sterile.

Multilanguage box: GB, FR, IT, ES, DE, PT, NL, SE, DK, RU, GR.

Minimum order: box of 100 pcs.

Technical Specifications:

- Colour: Grey
- Depth of penetration: 1.8 mm
- Entire needle Gauge: G21
- Needle tip Gauge: G23
- Blood flow: 10-20 µl
- Test:
 - Finger Stick
 - Glucose



GIMA

SURGILANCE SAFETY NEEDLE G22 - automatic lancets

Code: 24515
Category: Lancets
Unit of sale: box of 100 pcs.
Minimum order: 1
Type: Medical device
Class: II A
NSIS: 16427
CND: V9009
EAN13: 8023279245158



Description: Multi purpose capillary blood sampling devices for all testing requirements. The one-step safety lancet is easier to use, no arming is required, and safer, once lancet is used it is rendered inoperable. High-speed delivery and penetration method minimizes patient pain and operator error.

Latex-free, hypo-allergenic, disposable, sterile.

Multilanguage box: GB, FR, IT, ES, DE, PT, NL, SE, DK, RU, GR.

Minimum order: box of 100 pcs.

Technical Specifications:

- Colour: Orange
- Depth of penetration: 2.2 mm
- Entire needle Gauge: G21
- Needle tip Gauge: G22
- Blood flow: 20-40 µl
- Test:
 - Finger Stick
 - Glucose
 - Hematocrit