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

The undersigned declares that the products described in this document meet the Council Directive provisions that apply to them and the CE Mark may be affixed.

Product Description:	**SurgiLance™ Safety Lancet**
GMDN- Code:	**61578**
Intended Purpose:	**Single-use lancing device for finger-stick and blood collection procedures**
Model No's:	**SLN100, SLN170, SLN200, SLN240, SLN300, SLB200, SLB250, SLN100S, SLN170S, SLN200S, SLN240S, SLN300S, SLB200S, SLB250S, SLN302, SLN304, SLN304W, SLB254, SLB254, SLN1030, SLN3010, SLB204, SLN242**

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 IIa** Rule: **6** (MDD 93/42/EEC Annex IX)

Manufacturer :	**MediPurpose Pte. Ltd.**
Address :	**10 Anson Road** **#12-08 International Plaza, Singapore 079903**
EU Authorized Representative:	**Advena Limited.** **Tower Business Centre, 2nd Flr., Tower Street,** **Swatar, BKR 4013 Malta.**

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.

This present declaration is also in conformity with the list of applicable standards/and common specifications (CS) stated in Appendix I.

Adeline Yi, Director QA/RA

6 Apr 2023
Date

Appendix I – Applicable Standards
This present declaration is also in conformity with the following European standards and Common Specifications (CS):

Standard/CS/Document Name	Description
EN ISO 20417	Medical devices- Information to be supplied by the manufacturer
EN ISO 10993-1	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
EN ISO 10993-4	Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood
EN ISO 10993-5	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-10	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
EN ISO 10993-11	Biological evaluation of medical devices – Part 11: Tests for systemic toxicity
EN ISO 11137-1	Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
EN ISO 11137-2	Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose
EN ISO 11607-1	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2	Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 11737-1	Sterilization of medical devices – Microbiological methods – Part 1: Determination of a population of microorganisms on products
EN ISO 13485	Medical devices – Quality management systems – Requirements for regulatory purposes
EN ISO 14971	Medical devices – Application of risk management to medical devices
EN ISO 15223-1	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
EN 62366-1	Medical devices. Application of usability engineering to medical devices
MDD 93/42/EEC	Council Directive concerning medical devices as amended by Directive 2007/47/EC
TG(MD)R	Australia Therapeutic Goods (Medical Devices) Regulations 2002

*Refer to the product technical file for the published year/revision of the standard.