DECLARATION OF CONFORMITY

We, SteriLance Medical (Suzhou) Inc. as the Product Owner, hereby declare that the below mentioned devices have been classified according to the classification rules and conform to the Essential Principles for Safety and Performance as laid out in the Medical Device Regulations in Thailand according to the Medical Device Act B.E. 2551 (2008) and the amended Medical Device Act B.E. 2562 (2019), 2nd edition.

Name and Address of Product Owner:

SteriLance Medical (Suzhou) Inc. No.168,PuTuoShan Road,New District 215153,Suzhou, Jiangsu, P.R.China

Name and Address of Physical Manufacturer:

SteriLance Medical (Suzhou) Inc. No.168,PuTuoShan Road,New District 215153,Suzhou, Jiangsu, P.R.China

Name and Address of Authorized Distributor:

Greiner Bio-One Thailand Ltd.
700 / 172 Moo. 1, Amata Nakorn Industrial Estate, Tambon Bankao, Amphur Phanthong,
Chonburi, Thailand 20160

Medical Device(s):

Product name	Product code	Product description
MiniCollect PIXIE Heel Incision Safety Lancet	450525	Colour coding light green, Incision length 1.40 mm., Penetration depth 0.65 mm.
MiniCollect PIXIE Heel Incision Safety Lancet	450526	Colour coding orange, Incision length 1.75 mm., Penetration depth 0.85 mm.
MiniCollect PIXIE Heel Incision Safety Lancet	450527	Colour coding yellow, Incision length 2.50 mm., Penetration depth 1 mm.

Risk Classification: Class 2 rule 6

Quality Management System Certificate:

Certification Body : TUV Rheinland LGA Products GmbH;

Certificate Number : SX 2013202-1

Issue date : 2021-02-26

Expiry date : 2024-02-28

Standards Applied:

No.	Document Number	Document Title
1.	EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes

2.	EN ISO 15223-1:2016	Medical devices - symbols to be used with medical device labels, labelling and information to be supplied - part 1: general requirements
3.	EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices
4.	EN ISO 14971:2019	Medical devices — Application of risk management to medical devices
5.	EN ISO 10993-1:2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
6.	EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
7.	EN ISO 10993-10:2013	Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization
8.	EN ISO10993-11:2018	Biological evaluation of medical devices - Part 11:Tests for systemic toxicity
9.	EN ISO10993-12:2012	Biological evaluation of medical devices – Part 12 :Sample preparation and reference materials
10.	IEC 62366-1:2020	Medical devices - Application of usability engineering to medical devices
11.	EN ISO 14644-1:2015	Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration
12.	EN ISO 14644-2:2015	Cleanrooms and associated controlled environments. Part 2:Monitoring to provide evidence of cleanroom
13.	EN ISO 14698-1:2003	Cleanrooms and associated controlled environments - Biocontamination control - Part 1: General principles and methods (ISO 14698-1:2003)
14.	EN ISO 14698-2:2003	Cleanrooms and associated controlled environments - Biocontamination control - Part 2: Evaluation and interpretation of biocontamination data (ISO 14698-2:2003)
15.	EN ISO 11607-1:2020	Packaging for terminally sterilized medical devices -- Part 1: Requirements for materials, sterile barrier systems and packaging systems
16.	EN ISO 11607-2:2020	Packaging for terminally sterilized medical devices -- Part 2: Validation requirements for forming, sealing and assembly processes
17.	EN ISO 11737-1:2018	Sterilization of medical devices – Microbiological methods – Part 1: Determination of a population of microorganisms on products
18.	EN ISO 11737-2:2020	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
19.	EN ISO 11137-1:2015	Sterilization of health care products -Radiation -Part 1:

		Requirements for development, validation and routine control of a sterilization process for medical devices
20.	EN ISO 11137-2:2015	Sterilization of health care products -Radiation -Part 2: Establishing the sterilization dose
21.	EN 556-1:2001/AC:2006	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices
22.	EN ISO 7153-1:2016	Surgical instruments —Materials Part 1: Metals
23.	ASTM D4169-2016	Standard Practice for Performance Testing of Shipping Containers and Systems
24.	MEDDEV 2.7.1 Rev.4	Clinical evaluation: Guidance under the Directive 93/42 / EEC and 90/385 / EEC manufacturers and notified bodies
25.	MDD 93/42/EEC	Medical Device Directive 93/42/EEC

This declaration of conformity is valid from 25th ,Feb.25

Authorized Signatory:

Liu Guohua

Liu Guohua,Quality Manager

2022-02-25

Date