

Declaration of Conformity

This European Declaration of Conformity is issued under the sole responsibility of the manufacturer.

MANUFACTURER		
Name of Company	Address	SRN
SteriLance Medical(Suzhou)Inc.	No.168 PuTuoShan Road,New District,215153 Suzhou,Jiangsu, PEOPLE'S REPUBLIC OF CHINA	CN-MF-000002860

AUTHORIZED REPRESENTATIVE			
Name of Company	Address	SRN	Phone/email
Emergo Europe B.V.	Westervoortsedijk 60 6827 AT Arnhem The Netherlands	NL-AR-000000116	+31.70.345.8570 EmergoEurope@ul.com

PRODUCT IDENTIFICATION		
Product Name	Model	EMDN Code
Disposable Safety Lancets	Press Plus	V010401
Intended Purpose		Basic UDI-DI
The safety lancet is used for capillary blood collection.		6945630105BH

RISK CLASS FOR MEDICAL DEVICES		
Device Classification		Common Specifications / Standards
Class:	Ila	Medical Devices Regulation (EU) 2017/745
Rule:	6	

NOTIFIED BODY			
Name of Company	ID Number	Conformity Assessment Procedure	Certificate Reference(s)
TÜV SÜD Product Service GmbH	 0123	Medical Devices Regulation (EU) 2017/745 ,Annex IX Chapters I and III	Certificate No.: G10 093119 0001 Rev.02 Valid from: 2025-07-11 Valid until: 2027-11-23

The SteriLance Medical(Suzhou)Inc. declares that the above-mentioned products meet the provision of the following EU legislation:

Medical Devices Regulation (EU) 2017/745

COMPANY REPRESENTATIVE: Ju Junlong

TITLE: Quality Manager

SIGNATURE:



PLACE: Suzhou

DATE:

2025-12-02

Annex 1 Product List

No.	Product Name	Model	Specifications	Product Code
1.	Disposable Safety Lancets	Press Plus	17G 1.2mm	05-231712B
2.			17G 1.5mm	05-231715B
3.			17G 1.8mm	05-231718B
4.			17G 2.0mm	05-231720B
5.			17G 2.2mm	05-231722B
6.			17G 2.4mm	05-231724B
7.			17G 2.8mm	05-231728B
8.			18G 1.2mm	05-231812B
9.			18G 1.5mm	05-231815B
10.			18G 1.8mm	05-231818B
11.			18G 2.2mm	05-231822B
12.			18G 2.4mm	05-231824B
13.			18G 2.8mm	05-231828B
14.			21G 1.2mm	05-232112
15.			21G 1.5mm	05-232115
16.			21G 1.8mm	05-232118
17.			21G 2.2mm	05-232122
18.			21G 2.4mm	05-232124
19.			21G 2.8mm	05-232128
20.			23G 1.2mm	05-232312
21.			23G 1.5mm	05-232315
22.			23G 1.8mm	05-232318
23.			23G 2.2mm	05-232322
24.			23G 2.4mm	05-232324
25.			23G 2.8mm	05-232328
26.			26G 1.2mm	05-232612
27.			26G 1.5mm	05-232615
28.			26G 1.8mm	05-232618
29.			26G 2.2mm	05-232622
30.			26G 2.4mm	05-232624
31.			26G 2.8mm	05-232628
32.			28G 1.2mm	05-232812
33.			28G 1.5mm	05-232815
34.			28G 1.8mm	05-232818
35.			28G 2.2mm	05-232822
36.			28G 2.4mm	05-232824
37.			28G 2.8mm	05-232828
38.			30G 1.2mm	05-233012
39.			30G 1.5mm	05-233015
40.			30G 1.8mm	05-233018
41.			30G 2.2mm	05-233022
42.			30G 2.4mm	05-233024
43.			30G 2.8mm	05-233028