

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.	Prinsessegracht 20,2514 AP,The Hague,The Netherlands	NL-AR-00000011 6	+31.70.345.8570 EmergoEurope@ul.com

PRODUCT IDENTIFICATION		
Product Name	Type	Code / Catalog Number
Disposable Safety Lancets	Press,Press Plus,Press2, Press2 Plus,Impress,Impress Pro,Lite3,Flex3,UltraSafe,Elite	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	CE 0123	Medical Devices Regulation (EU) 2017/745 ,Annex IX Chapters I and III	Certificate No.: G10 093119 0001 Rev.00 Issue date: 2022-11-24 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: Zhang Xuanchao

TITLE: Quality Manager

SIGNATURE:

Zhang Xuanchao
2022-12-29

PLACE: Suzhou

DATE:

STERILANCE

Innovation for Safety

Medical device Name (trading name)	Individual Article number of the Device; One per Row	Device Basic UDI-DI	EMDN Code (most granular level)	MDA /MDN Code
Disposable Safety Lancets	Type: Press Plus; specification:18G 1.5mm Product code:05-231815B	6945630105BH	V010401	MDN 1208
Disposable Safety Lancets	Type: Press Plus; specification:21G 1.2mm Product code:05-232112	6945630105BH	V010401	MDN 1208
Disposable Safety Lancets	Type: Press Plus; specification:21G 1.8mm Product code:05-232118	6945630105BH	V010401	MDN 1208
Disposable Safety Lancets	Type: Press Plus; specification:21G 2.2mm Product code:05-232122	6945630105BH	V010401	MDN 1208
Disposable Safety Lancets	Type: Press Plus; specification:21G 2.8mm Product code:05-232128	6945630105BH	V010401	MDN 1208
Disposable Safety Lancets	Type: Press Plus; specification:23G 1.8mm Product code:05-232318	6945630105BH	V010401	MDN 1208
Disposable Safety Lancets	Type: Press Plus; specification:26G 1.8mm Product code:05-232618	6945630105BH	V010401	MDN 1208
Disposable Safety Lancets	Type: Press Plus; specification:28G 1.8mm Product code:05-232818	6945630105BH	V010401	MDN 1208
Disposable Safety Lancets	Type: Press Plus; specification:30G 1.8mm Product code:05-233018	6945630105BH	V010401	MDN 1208

