

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	Type	EMDN Code
Disposable Blood Lancets	Soft,Soft Pro,Soft5, Softsure, SoftSense	V010402
Intended Purpose	Basic UDI-DI	
The disposable blood lancet is used with lancing device to collect capillary blood from fingertip or alternate sites for blood glucose testing or other testing utilizing small amounts of blood.		6945630101B9

RISK CLASS FOR MEDICAL DEVICES

Device Classification		Common Specifications / Standards
Class:	IIa	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.01 Valid from: 2023-06-19 Valid until: 2027-11-23

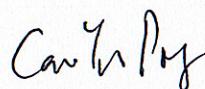
The SteriLance Medical(Suzhou)Inc. declares that the above-mentioned products meet the provision of the following EU legislation:

Medical Devices Regulation (EU) 2017/745

COMPANY REPRESENTATIVE: Cao Yueping

TITLE: PRRC

SIGNATURE:



PLACE: Suzhou

DATE:

