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:** Cao Yueping

PLACE: Suzhou **DATE:** 2023-06-19