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**
Heel Incision Safety Lancets	SteriHeel,SteriHeel Plus, Neoheel,OctaHeel	V010401
Intended Purpose		**Basic UDI-DI**
It is used for blood sampling form heels of infants during blood tests.		6945630130BG

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.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

PLACE: Suzhou **DATE:** 2022-12-29

Declaration of Conformity

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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**	**SARSTEDT´s trade name**	**SARSTEDT´s REF**
Heel Incision Safety Lancets	SteriHeel Plus	V010401	SafetyHeel®	85.1025 85.1026
Intended Purpose			**Basic UDI-DI**	
It is used for blood sampling form heels of infants during blood tests.			6945630130BG	

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 Yue Ping

PLACE: Suzhou **DATE:** 2023-07-03