

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		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

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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:	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.01 Valid from: 2023-06-19 Valid until: 2027-11-23

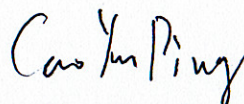
The SteriLance Medical(Suzhou)Inc. declares that the above-mentioned products meet the provision of the following EU legislation:

Medical Devices Regulation (EU) 2017/745

COMPANY REPRESENTATIVE: Cao Yueping

TITLE: PRRC

SIGNATURE:



PLACE: Suzhou

DATE:

2023-07-03