

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 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	 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

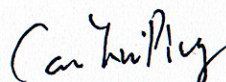
The SteriLance Medical(Suzhou)Inc. declares that the above-mentioned products meet the provision of the following EU legislation:

Medical Devices Regulation (EU) 2017/745

COMPANY REPRESENTATIVE: Cao Yueping

TITLE: PRRC

SIGNATURE:



PLACE: Suzhou

DATE:

2023-07-03
1/2

Annex Product List

Sterilance REF	Vitrex Product Name	Vitrex REF
05-061818B	Vitrex® Sterilance PRESS II Sterile Safety Lancets, 18G –1.8mm Blade -Green,100 pcs	393213
05-062618	Vitrex® Sterilance PRESS II Sterile Safety Lancets, 26G – 1.8mm - Yellow, 100 pcs	394213
05-062122	Vitrex® Sterilance PRESS II Sterile Safety Lancets, 21G – 2.2mm - Orange, 100 pcs	395213
05-062128	Vitrex® Sterilance PRESS II Sterile Safety Lancets, 21G – 2.8mm – Pink, 100 pcs	396213
05-062118	Vitrex® Sterilance PRESS II Sterile Safety Lancets, 21G – 1.8mm – Blue, 100 pcs	397213
05-062818	Vitrex® Sterilance PRESS II Sterile Safety Lancets, 28G – 1.8mm – Purple, 100 pcs	398213
05-063018	Vitrex® Sterilance PRESS II Sterile Safety Lancets, 30G – 1.8mm – Turquoise, 100 pcs	399213
05-161720B	Vitrex® Sterilance Ultrasafe Safety Lancets, 17G –2.0mm Blade -Green,100 pcs	393413
05-162618	Vitrex® Sterilance Ultrasafe Sterile Safety Lancets, 26G – 1.8mm - Yellow, 100 pcs	394413
05-162122	Vitrex® Sterilance Ultrasafe Sterile Safety Lancets, 21G – 2.2mm - Orange, 100 pcs	395413
05-162128	Vitrex® Sterilance Ultrasafe Sterile Safety Lancets, 21G – 2.8mm – Pink, 100 pcs	396413
05-162118	Vitrex® Sterilance Ultrasafe Sterile Safety Lancets, 21G – 1.8mm – Blue, 100 pcs	397413
05-162828	Vitrex® Sterilance Ultrasafe Sterile Safety Lancets, 28G – 2.8mm – Purple, 100 pcs	398413
05-111818B	Vitrex® Sterilance LITE III Sterile Safety Lancets, 18G – 1.8mm Blade - Green,100 pcs	373213
05-112818	Vitrex® Sterilance LITE III Sterile Safety Lancets, 28G – 1.8mm – Purple, 100 pcs	374213
05-112618	Vitrex® Sterilance LITE III Sterile Safety Lancets, 26G – 1.8mm - Yellow, 100 pcs	375213
05-112624	Vitrex® Sterilance LITE III Sterile Safety Lancets, 26G – 2.4mm – Blue, 100 pcs	376213
05-112118	Vitrex® Sterilance LITE III Sterile Safety Lancets, 21G – 1.8mm – Orange, 100 pcs	377213
05-112124	Vitrex® Sterilance LITE III Sterile Safety Lancets, 21G – 2.4mm – Pink, 100 pcs	378213
05-1523A	Vitrex® Flex 3 23G– 1.2/1.8/2.4mm, 100 pcs	395813
05-1526A	Vitrex® Flex 3 26G – 1.2/1.8/2.4mm, 100 pcs	396813
05-1528A	Vitrex® Flex 3 28G – 1.2/1.8/2.4mm, 100 pcs	397813