

Declaration of Conformity

This European Declaration of Conformity is issued under the sole responsibility of the manufacturer.

MANUFACTURER

Name of Company	Address	SRN
Sandstone Medical (Suzhou) Inc.	Buliding 6, No.168 PuTuoShan Road,New District, 215153 Suzhou,Jiangsu, PEOPLE'S REPUBLIC OF CHINA	CN-MF-000011105

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	Model	EMDN code	Intended Purpose		
Safety Pen Needles	HS	A0101010201	The pen needle is intended for use with pen injector devices for subcutaneous injection of drugs.		
Product code			MDN code	MDS code	Basic UDI-DI
05-3005; 05-3006; 05-3008; 05-3105; 05-3106; 05-3108; 05-3204; 05-3205; 05-3206; 05-3304; 05-3305;			MDN 1202	MDS 1005	697285729052C

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 103844 0005 Rev. 00 Valid from: 2024-09-12 Valid until: 2029-09-11

The Sandstone 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: Susan Sun

TITLE: Quality Manager

SIGNATURE:

Susan Sun

PLACE: Suzhou

DATE:

2024-10-08