CE Technical Documentation

EU Declaration of Conformity

According to Regulation (EU) 2017/745 Annex II and III

Blood Lancet for Single Use

Basic UDI-DI :Model XY：69340479EU01RQ

Model XH：69340479EU01XHM6

Model XA：69340479EU01XALQ

Model BY：69340479EU01BYL6

Revision History

Current version	Issue date	Effective date	Previous version	Contents changed
05	2024.02.05	2024.02.05	04	Update Certificate information.
04	2023.09.25	2023.09.25	03	Updated Trading name.
03	2023.01.17	2023.01.17	02/00	Update Basic UDI-DI.
02/00	2022.01.20	2022.01.20	01/00	Update the CE TD according to MDR.

Approval Sheet

Performed by	Name	Signature	Date
Author	Chi Huang	Huang Chi	2024.02.05
Reviewer	Ping Liu	Liu Ping	2024.02.05
Approver	Zhicheng Chen	Chen Zhi Cheng	2024.02.05

EU Declaration of Conformity

According to Art. 19 of Regulation (EU) 2017/745 on Medical Devices

Manufacturer:	Name: Ningbo Medsun Medical Co., Ltd. Address: No.55 Jinxi Road, Zhenhai, 315221, Ningbo, P.R.China Tel: 0086-574-86301778 Fax: 0086-574-86301708
SRN:	CN-MF-000011842
European Representative:	Name: Shanghai International Holding Corp. GmbH (Europe) Address: Eiffestrasse 80, 20537 Hamburg, Germany Tel: 0049-40-2513175 Fax: 0049-40-255726 Email:shholding@hotmail.com
SRN:	DE-AR-000000001
Product name：	Blood Lancet for Single Use
Trade name:	Model XY,Model XH,Model XA:Sterile Safety Lancet、Safety Lancet Model BY:Lancet
Model：	BYY,BYY1,BYY2,BYY3,BYY4,BYB XY1,XY2,XY3,XY4,XY1 Blade,XY2 Blade,XY3 Blade,XY4 Blade XH1,XH2,XH3,XH4,XH5,XH6,XH1Blade,XH2 Blade,XH3 Blade,XH4 Blade,XH5 Blade,XH6 Blade XA1,XA2,XA3,XA4
Size：	**Needle type：** 18G-33G， **Blade：** 1.5mm,1.2mm,1.1mm,0.9mm,0.8mm
Basic UDI-DI :	Model XY：69340479EU01RQ Model XH：69340479EU01XHM6 Model XA：69340479EU01XALQ Model BY：69340479EU01BYL6

CND Code:	Model XY,XH,XA：V010401 Model BY：V010402
UMDNS Code:	10440
Classification of product:	Class IIa, Rule 6
Conformity assessment procedure:	Regulation (EU) 2017/745 Annex IX

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/745 on Medical Devices (MDR). All supporting documentations are retained under the premises of the manufacturer.

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany

NB Identification number: 0123

CE Certificate No.: G10 072777 0016 Rev.00

Expire date of the Certificate: 2029-02-04

Start of CE Marking: 2024-02-05

Place Issue: Ningbo, Zhejiang, China

Date of Issue: 2024-02-05

Signature: Chen Zhi Chang

Position: General Manager