

Ningbo Medsun Medical Co.,Ltd.		
Title: CE Technical Documentation EU Declaration of Conformity (Blood Lancet for Single Use)	Compiling Dept: Technology Dept.	NO.: CE-MDR-001-01
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# 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


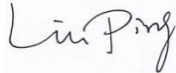

Model XA: 69340479EU01XALQ

Model BY: 69340479EU01BYL6

### Revision History

Current version	Issue date	Effective date	Previous version	Contents changed
06	2024.03.22	2024.03.22	05	Update the address and certificate version.
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		2024.03.22
Reviewer	Ping Liu		2024.03.22
Approver	Zhicheng Chen		2024.03.22

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## 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.298 Huangjipu Road, Jiangbei, 315031, Ningbo, PEOPLE'S REPUBLIC OF 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  
BYY,BYY1,BYY2,BYY3,BYY4,BYB

**Model:** 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

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**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

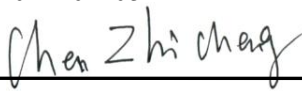
**CE Certificate No.:** G10 072777 0016 Rev.01

**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:**  \_\_\_\_\_

**Position:** General Manager