

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
Page: 1/3	Edition/Revision:06	Issue Date:2024.03.22

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

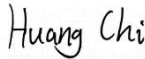
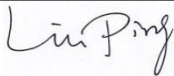
Model XA: 69340479EU01XALQ

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: Eifffestrasse 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,XH1 Blade,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

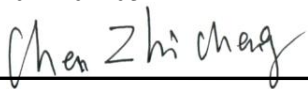
CE Certificate No.: G10 072777 0016 Rev.01

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