

# Declaration of Conformity

## Manufacturer:

Name: Ningbo Medsun Medical Co., Ltd.  
Address: No.55 Jinxi Road, Zhenhai, 315221, Ningbo, P.R.China  
Tel: 0086-574-86301887  
Fax: 0086-574-86301778

## EC-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

**Product name:** Blood Lancet for Single Use

**Model:** BYY, BYY1, BYY2, BYY3, BYY4, BYB, BD, Z, XF1, XF2, XT1, XT2, XTL1, XTL2, XTT1, XTT2, XY1, XY2, XY3, XY4, XY1Blade, XY2Blade, XY3Blade, XY4Blade, XYC1, XYC2, XYL1, XYL2, XH1, XH2, XH3, XH4, XH5, XH6, XH1Blade, XH2Blade, XH3Blade, XH4Blade, XH5Blade, XH6Blade, XA1, XA2, XA3, XA4, XA5, XA6, XA7, XA8

**UMDNS Code:** 10440

**Classification of product:** Class IIa, Rule 6

**Conformity Assessment Route:** Annex V.3 of MDD93/42/EEC

We herewith declare in our own responsibility that the above-mentioned product(s) meet(s) the provisions of the Council Directive 93/42/EEC of 14th June concerning medical devices, amended by Council Directive 2007/47/EC. All supporting documentation is retained under the premises of the manufacturer. The declaration of conformity is issued under our sole responsibility.

## Directives

**General applicable directives:** MDD 93/42/EEC.

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

**NB Identification number:** 0123

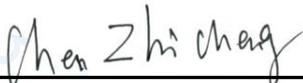
**EC Certificate CE:** G2 072777 0009 Rev.01

**Expire date of the Certificate :** 2024-5-26

**Start of CE Marking :** 2010-4-10

**Place Issue:** Ningbo, China

**Date of Issue:** 2021.01.04

**Signature:** 

**Position:** General Manager