NO. 55 Jinxi Road, Zhenhai, Ningbo, China 315221

Tel: 86-574-86301708 Fax: 86-574-86301778

01 Declaration of Conformity

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

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

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 CE: 2010-4-10

Place, Date of Issue: Ningbo, China

Signature: Then Zhitheng

Position: General Manager