Revision History 历史页

Current version 现有版本	Issue date 发布日期	Effective date 生效日期	Previous version 替换版本	Contents changed 修改内容
02	2023.11.29	2023.11.29	01/00	细化 Z 型采血针的分类 Refining the classification of Z-type blood collection needles
01/00	2021.01.04	2021.01.04	/	修订原 CE 技术文件的格式，各章节形成独立文档，版本从 01/00 开始。 增加 XA1-XA8 型号信息。 Revise the format of the original CE technical file, each chapter forms an independent document, the version starts from 01/00. Added XA1-XA8 model information.

Approval Sheet 批准表

Performed by 执行者	Name 名字	Signature 签名	Date 日期
Author 作者	Chi Huang	Huang Chi	2021.01.04
Reviewer 评审者	Ping Liu	Liu Ping	2021.01.04
Approver 批准者	Zhicheng Chen	Chen Zhi cheng	2021.01.04

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
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Product name: Blood Lancet for Single Use
Model： BYY、BYY1、BYY2、BYY3、BYY4、BYB、BD、ZF1、ZF2、ZF3、ZF1 Blade、ZF2 Blade、ZF3 Blade、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: 2023.11.29

Signature: Chen Zhi Chang
Position: General Manager