01 Declaration of Conformity 符合性声明

Manufacturer: 生产商

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EC-Representative: CE 代表

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Product name 产品名称: Blood Lancet for Single Use 一次性使用采血针
Model 型号：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 编码: 10440
Classification of product 产品分类: Class IIa, Rule 6
Conformity Assessment Route 符合性评估路径: 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.

我们在此自行声明，上述产品符合理事会指令 2007/47 / EC 修订的 6 月 14 日理事会指令 93/42 / EEC 关于医疗器械的规定。 所有支持文档均保留在生产商的场所内。 符合性声明由我们自行负责。

Directives 指令

General applicable directives 适用指令: MDD 93/42/EEC.
Notified Body 公告机构: TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany
NB Identification number 公告机构编码: 0123
EC Certificate CE 证书编号: G2 072777 0009 Rev.01
Expire date of the Certificate 证书失效日期: 2024-5-26
Start of CE Marking CE 标志起用日: 2010-4-10
Place, Date of Issue 发行地点，日期: Ningbo, China 中国宁波

Signature 签名: Chen Zhi chang
Position 职位: General Manager 总经理