CERTIFICATE

Of Conformity
Low Voltage Directive 2014/35/EU

Registration No.: AT0116011093S

Report No.: R0116011093S
R0116011143S

Applicant	:	**Shenzhen Bestman Instrument Co., Ltd.** 4/F, Block 210, 2nd Industrial Area of Nanyou, Xiangnan Rd. Nanshan Dist., Shenzhen China.
Product	:	**Disposable Syringe Destroyer**
Identification	:	**Model No.** : **BD-300B, BD-300C**
		Trade Mark :
		Rating : **100-240VAC, 50/60Hz, Max.130W**
Test Standards	:	**EN 61010-1: 2010**

The certificate of conformity is based on an evaluation of a sample of the above mentioned product. Technical report and documentation are at the applicant's disposal. This is to certify that the tested sample is in conformity with Low Voltage Directive 2014/35/EU relating to electrical equipment designed for use within certain voltage limits. The certificate does not imply assessment of the series-production of the product. The applicant of the certificate is authorized to use this certificate in connection with EU declaration of conformity specified in Article 15 and Annex IV of the Directive.

ANBOTEK Anbotek CERTIFICATE

Certified by

EC Declaration of Conformity

Manufacturer:

Name: Shenzhen Bestman Instrument Co., Ltd.
Address:8th Floor,Yifang Building, No.315 Shuangming Avenue,Dongzhou Community, Guangming Street,Guangming District,Shenzhen,China
SRN: CN-MF-000031725

whose single Authorized Representative:

Name: Lotus NL B.V.
Address:Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands

We, the manufacturer, herewith declare that the products

Product Name:DISPOSABLE SYRINGE DESTROYER

Model/Type:BD-300B/300C/310/320/320A

meet the provisions of Medical Device Regulation 2017/745 which apply to them.

The medical device has been assigned to **class I**.

CE

The product concerned has been manufactured under a quality management system according to Chapter I, Chapter III of Annex IX of Medical Device Regulation 2017/745.

Quality Management System Certificate:
Standards Applied: ISO13485:2016, ISO9001:2015
Notified Body: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands

following the procedure relating to the EC Declaration of Conformity set out in Annex IV of Medical Device Regulation 2017/745.

The device that is covered by the present declaration is in conformity with this Regulation and, if applicable, with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity

The above mentioned declaration of conformity is exclusively under the sole responsibility of
Company: Shenzhen Bestman Instrument Co., Ltd.
Address: 8th Floor,Yifang Building, No.315 Shuangming Avenue,Dongzhou Community, Guangming Street,Guangming District,Shenzhen,China

Shenzhen City, 2025.04.23 General Manager

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

持有证书 ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:
兹证明

Shenzhen Bestman
Instrument Co., Ltd.
8th Floor, Yifang Building
No. 315 Shuangming Avenue, Dongzhou
Community
Guangming Street, Guangming District
Shenzhen
Guangdong
518107
China

深圳市贝斯曼精密仪器有限公司
91440300731109384K
中国
广东省
深圳市
光明区光明街道
东周社区双明大道315号
易方大厦8层
邮编：518107

Holds Certificate No:
持有证书

MD 601051

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:
并运行符合 ISO 13485:2016 & EN ISO 13485:2016 要求的质量管理体系，认证范围如下：

Design, manufacture and sales of Ultrasound detecting Equipment, Ultrasound Series Vascular Doppler Detectors, Maternal/Fetal Monitor Equipment, Ultrasound Series Doppler FHR (Fetal Heart Rate) Detectors, Blood and Infusion Warmers, Disposable Syringe Destroyers, enteral feeding pumps and vein finders, Fingertip pulse oximeters.
超声检测设备、超声多普勒血流检测仪、胎儿/母亲监护仪、超声多普勒胎心音仪、输血输液加温器,注射器毁形器、喂养泵和静脉查找仪、指夹式脉搏血氧仪的设计，制造和销售。

For and on behalf of BSI:
BSI代表：

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date 首次发证日期： 2012-10-01
Latest Revision Date 最新发证日期： 2024-09-20
Effective Date 生效日期： 2024-09-28
Expiry Date 有效期至： 2027-09-27

bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

持有证书 ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:
兹证明

Shenzhen Bestman Instrument Co., Ltd.
8th Floor, Yifang Building
No. 315 Shuangming Avenue, Dongzhou Community
Guangming Street, Guangming District
Shenzhen
Guangdong

深圳市贝斯曼精密仪器有限公司
91440300731109384K
中国
广东省
深圳市
光明区光明街道
东周社区双明大道315号

医疗器械产品出口销售证明书附页

ATTACHMENT OF CERTIFICATE FOR EXPORTATION OF MEDICAL PRODUCTS

证书编号 Certificate No.：粤食药监械出 20240896 号

出口销售证明专用章

序号 SN	产品名称 Product（s）	规格型号 Model	注册证号 Registration certificate(s)
1	超声多普勒血流检测仪 Vascular Doppler Detector	BV-520、BV-520T、BV-520P、BV-550、BV-620V、BV-620VP、BV-620T、BV-660、BV-660P、BV-660T、BV-520P+、BV-520T+ BV-520、BV-520T、BV-520P、BV-550、BV-620V、BV-620VP、BV-620T、BV-660、BV-660P、BV-660T、BV-520P+、BV-520T+	粤械注准 20172071863
2	超声多普勒胎儿/母亲监护仪 Maternal/Fetal Monitor Equipment	BFM-700、BFM-700+、BFM-700E、BFM-700E+、BFM-700A、BFM-700M BFM-700、BFM-700+、BFM-	粤械注准 20182180651

bsi.

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 602263**

Issued To:

Shenzhen Bestman Instrument Co., Ltd.
8th Floor, Yifang Building
No. 315 Shuangming Avenue, Dongzhou Community
Guangming Street, Guangming District
Shenzhen
Guangdong
518107
China

In respect of:

Design and manufacture of Ultrasound Series Vascular Doppler Detectors, Electrocardiograph Equipment, Maternal/Fetal Monitor Equipment, Ultrasound Series Doppler FHR Detectors and Enteral Feeding Pumps.