By Royal Charter

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.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2013-11-13** Date: **2020-09-29** Expiry Date: **2023-11-12**

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

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 602263**
Date:	**2020-09-29**
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**

Subcontractor:	**Service(s) supplied**
Lotus NL B.V. Koningin Julianaplein 10 1e Verd 2595AA The Hague Netherlands	**EU Representative**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 602263**

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Date	Reference Number	Action
13 November 2013	8065801	First Issue.
15 August 2014	8206945	Change of EU representative to 'Lotus Medical Equipment Limited'.
14 November 2016	8638531	Extension of scope to cover 'enteral feeding pumps'.
18 February 2019	9659991	Renewal and removal of `Blood and Infusion Warmers`.
22 March 2019	9755819	Traceable to NB 0086.
Current	3291434	Change of manufacturer address to 'No. 315 Shuangming Avenue, Dongzhou Community, Guangming Street, Guangming District, Shenzhen' Change of EU Representative to 'Lotus NL B.V., Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands'