

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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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

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List of Significant Subcontractors

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

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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

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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'