

EC Certificate - Full Quality Assurance System

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

No. CE 650109
Issued To: **Shanghai Shape Memory Alloy Co., Ltd.**
1F and 5F, Tower 41
No. 258 XinZhuan Road
Songjiang High-Tech Park
CaoHeJing Development District
Shanghai
201612
China

In respect of:

The design, development and manufacture of Occluders and related Delivery Systems, and Snares.

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: **2016-11-24**

Date: **2020-05-04**

Expiry Date: **2024-05-26**

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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.

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Supplementary Information to CE 650109

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Number	Device Name	Intended purpose per IFU
Class III		
---	MemoPart™ ASD, PDA, VSD, PFO, Plug Occluders and related Delivery Systems. MemoPart™ Snares	See CE 650110

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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
BQ Plus Medical Co., Ltd. No.18, Che Ye Road Che Dun Town, Songjiang 201611 Shanghai China	ETO Sterilization
Lepu Medical (Europe) Cooperatief U.A. Abe Lenstra Boulevard 36 8448 JB, Heerenveen The Netherlands	EU Representative

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EC Certificate - Full Quality Assurance System Certificate History

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Date	Reference Number	Action
24 November 2016	8486062	First issue.
01 March 2019	8250592	Traceable to NB 0086.
Current	3163693	Certificate renewal. Addition of product table. Correction of the ETO sterilization subcontractor from NELSON Techno Medical Co., Ltd. to BQ Plus Medical Co., Ltd.