



EC Certificate - Full Quality Assurance System

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

No. **CE 684927**
Issued To: **Wallaby Medical, Inc.**
23181 Verdugo Drive
Suite 104-A
Laguna Hills
California
92653
USA

In respect of:

Design, development, manufacture and distribution of detachable coil systems.

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: **2019-09-10**

Date: **2019-09-10**

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 684927

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Number	Device Name	Intended purpose per IFU
Class III		
---	Wallaby Avenir Coil System	See CE 684926

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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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List of Significant Subcontractors

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

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Subcontractor:	Service(s) supplied
Emergo Europe Prinsessegracht 20 2514 AP The Hague The Netherlands	EU Representative
Shanghai Wallaby Medical Technologies Co., Inc. Room 201, No.2 Lane 166 Tianxiong Road Pudong New Area Shanghai 201318 China	Manufacture
Synergy Health (Suzhou) Sterilization Technologies, Ltd. NO. 26 Xinchang Road, Suzhou Industrial Park Jiangsu 215125 China	ETO Sterilization

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Certificate History

Certificate No: **CE 684927**
Date: **2019-09-10**
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Date	Reference Number	Action
Current	8863131	First Issue

