

EC Certificate - Full Quality Assurance

Directive 90/385/EEC on Active Implantable Medical Devices, Annex 2, excluding Section 4

No. CE 548726
Issued To: **Avery Biomedical Devices (ABD), Inc.**
61 Mall Drive
Commack
New York
11725
USA

In respect of:

The design, development and manufacture of implanted diaphragm pacemaker systems

on the basis of our examination of the quality assurance system under the requirements of Council Directive 90/385/EEC, Annex 2, excluding Section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of devices covered by this certificate an EC design-examination certificate according to 90/385/EEC, Annex 2, section 4 is required.

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



Albert Roossien, Regulatory Lead

First Issued: **2010-04-28**

Date: **2019-02-25**

Expiry Date: **2020-04-27**

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Page 1 of 1

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
Advena Ltd. Pure Offices, Suite #35 Plato Close, Tachbrook Park Warwick CV34 6WE United Kingdom	EU Representative
Alfa Aesar 26 Parkridge Road Ward Hill Massachusetts USA	Crucial Supplier
Life Science Outsourcing, Inc 830 Challenger Street Brea California 92821 USA	Moist Heat Sterilization

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Subcontractor:	Service(s) supplied
NuSil Technology Inc. 1050 Cindy Lane Carpinteria California USA	Crucial Supplier
Saint-Gobain Performance Plastics 3910 Terry-Diane Street Beaverton Michigan 48612 USA	Crucial Supplier
Sigmund Cohn Corp. 121 South Columbus Mount Vernon New York USA	Crucial Supplier

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Speciality Silicone Fabricators 3077 Rollie Gates Drive Paso Robles California 93446 USA	Crucial Supplier
Sterling Medical Devices, Inc. 17 Legion Place Rochelle Park New Jersey 07662 USA	Design Development

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EC Certificate - Full Quality Assurance Certificate History

Certificate No: **CE 548726**
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Date	Reference Number	Action
28 April 2010	7342940	First Issue.
28 April 2015	8244356	Certificate Renewal. Addition of Sterling Medical Devices, Inc. as significant subcontractor and first inclusion of Crucial Suppliers.
20 September 2017	8680873	Change/update the EU Representative.
Current	7780867	Traceable to NB 0086. Administrative wording update to subcontractor service from 'Sterilization' to 'Moist Heat' for the following subcontractors: Life Science Outsourcing, Inc.