

# 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):



Gary E Slack, Senior Vice President Medical Devices

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

Date: **2020-08-13**

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 548726

Issued To:

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Number	Device Name	Intended purpose per IFU
<b>Class III- AIMD</b>		
---	Implanted Diaphragm Pacemaker System	See CE 549647

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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**

Advena Ltd  
Tower Business Centre, 2nd Flr,  
Tower Street, Swatar, BKR 4013  
Malta

**EU Representative**

Life Science Outsourcing, Inc  
830 Challenger Street  
Brea  
California  
92821  
USA

**Moist Heat Sterilization**

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.
25 February 2019	7780867	Traceable to NB 0086. Administrative wording update to subcontractor service from 'Sterilization' to 'Moist Heat' for the following subcontractors: Life Science Outsourcing, Inc.
Current	3043268	Certificate Renewal. Addition of product table. Removal of crucial supplier for certificate: Alfa Aesar, Nusil Technology Inc, Saint-Gobain Performance Plastics, Sigmund Cohn Corp, and Specialty Silicone Fabricators. Change of EU Representative address.