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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EC Certificate - Full Quality Assurance

Supplementary Information to CE 548726

Issued To:

Avery Biomedical Devices (ABD), Inc.
61 Mall Drive
Commack
New York
11725
USA

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

First Issued: **2010-04-28** Date: **2020-08-13** Expiry Date: **2024-05-26**

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By Royal Charter

EC Certificate - Full Quality Assurance

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

List of Significant Subcontractors

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

Certificate No:	**CE 548726**
Date:	**2020-08-13**
Issued To:	**Avery Biomedical Devices (ABD), Inc.** **61 Mall Drive** **Commack** **New York** **11725** **USA**

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**

Date: **2020-08-13**

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61 Mall Drive
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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.