

# 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.

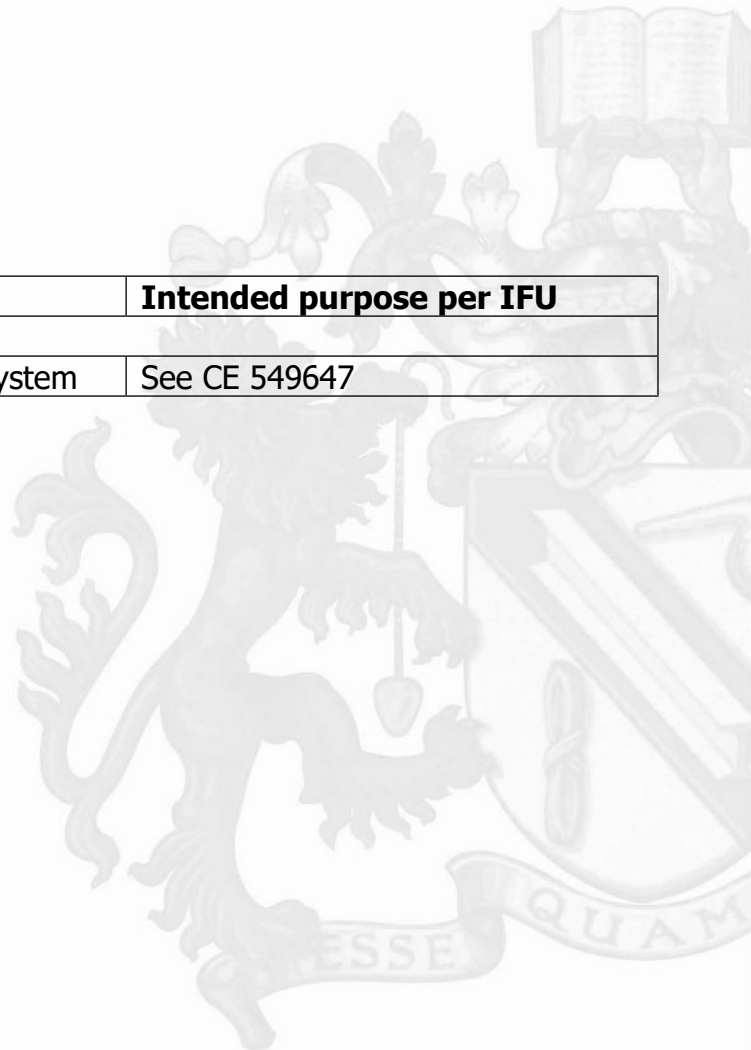
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## Supplementary Information to CE 548726

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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.

# EC Certificate - Full Quality Assurance Certificate History

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

| 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.<br>Administrative wording update to subcontractor service from 'Sterilization' to 'Moist Heat' for the following subcontractors: Life Science Outsourcing, Inc.   |
| 13 August 2020    | 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. |

**Non-significant changes approved after the 26<sup>th</sup> May 2021 as per the Transitional Provisions of MDR Article 120.3**

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| Date              | Reference Number | Action  |
|-------------------|------------------|---|
| 29 September 2023 | 30007530         | Address change for subcontractor Sterling Medical Devices.<br>Removal of all subcontractors listed on certificate |

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29 September 2023

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

To whom it may concern,

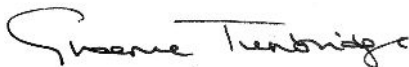
The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26<sup>th</sup> May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related AIMDD specified below remains valid until the expiry date specified on the certificate.

| <b>Certificate</b> | <b>Directive and Annex</b>                       | <b>Reference Number</b> | <b>Changes approved</b>   |
|--------------------|--|-------------------------|---|
| CE 548726          | 90/385/EEC<br>Annex 2,<br>excluding Section<br>4 | 30007530                | Address change for subcontractor Sterling Medical Devices.<br>Removal of all subcontractors listed on certificate |

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,



Graeme Tunbridge  
Senior Vice President, Medical Devices