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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EC Certificate - Full Quality Assurance Certificate History

Certificate No: **CE 548726**

Date: **2020-08-13**

Issued To: **Avery Biomedical Devices (ABD), Inc.**
61 Mall Drive
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. 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 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		

EC Certificate - Full Quality Assurance Certificate History

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

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

Inspiring trust for a more resilient world.

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 26th 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.

Certificate	**Directive and Annex**	**Reference Number**	**Changes approved**
CE 548726	90/385/EEC Annex 2, excluding Section 4	30007530	Address change for subcontractor Sterling Medical Devices. 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