EC Design-Examination Certificate

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

No. **CE 549647**

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

In respect of:

Implanted Diaphragm Pacemaker System

BSI has performed a design examination on the above devices in accordance with the Council Directive 90/385/EEC, Annex 2 Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex 2 excluding Section 4 certificate 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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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
N/A	External RF Transmitter	Spirit	The system is indicated for adult and pediatric patients who require chronic ventilatory support, and with the following conditions: i) Congenital Central Hypoventilation Syndrome (CCHS) ii) Congenital Central Sleep Apnoea iii) High cervical spinal cord injury iv) Brain stem injury or disease	AIMD
I-110A	Implantable RF Receiver	N/A		AIMD
E377-05	Implantable Electrode	N/A		AIMD
902A and/or 902AL	External RF Antenna	N/A		AIMD

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Certificate History

Date	Reference Number	Action
28 April 2010	10105342	First Issue.
20 July 2013	10142893	Addendum – modifications to the instruction manual.
28 April 2015	10154081	Certificate renewal.
20 September 2017	8680873	Replacement of Mark IV Transmitter with Spirit Transmitter.
25 February 2019	7780867	Traceable to NB 0086.
Current	3043269	Certificate Renewal. Update to include new format of certificate to include product table. The removal of acquired central sleep apnoea from the indications

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