EC Design-Examination Certificate

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

No. **CE 562872**

Issued To: **Inspire Medical Systems, Inc.**
5500 Wayzata Blvd, Suite 1600
Golden Valley
Minnesota
55416
USA

In respect of:

Implantable Pulse Generator and Accessories:
Implantable System for the Treatment of Periodic Breathing

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: **2010-10-20** Date: **2021-05-24** Expiry Date: **2024-05-26**

...making excellence a habit.™

EC Design-Examination Certificate

Supplementary Information to CE 562872

Issued To:

Inspire Medical Systems, Inc.
5500 Wayzata Blvd, Suite 1600
Golden Valley
Minnesota
55416
USA

Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
Model 3028	Inspire IV Upper Airway Stimulator	Model 3028	Inspire Upper Airway Stimulation therapy is intended to treat moderate to severe obstructive sleep apnea (15 ≤ AHI ≤ 65) by improving airway patency through stimulation of the hypoglossal nerve, synchronous with respiration, to elicit a neuromuscular response at the base of the tongue.	AIMD
Model 4063	Inspire Stimulation Lead	Model 4063		AIMD
Model 4340	Inspire Sensing Lead	Model 4340		AIMD
Model 2740	Inspire Programmer	Model 2740		AIMD
Model 2500	Inspire Sleep Remote	Model 2500		AIMD

First Issued: **2010-10-20** Date: **2021-05-24** Expiry Date: **2024-05-26**

...making excellence a habit.™

EC Design-Examination Certificate

Supplementary Information to CE 562872

Issued To:

Inspire Medical Systems, Inc.
5500 Wayzata Blvd, Suite 1600
Golden Valley
Minnesota
55416
USA

Certificate History

Date	Reference	Action
20 October 2010	10116696	First issue – including Physician Programmer Application Software Version 1.3 & OS Software Version 1.1. When joined with the Telemetry Head (OS Software Version 8.0) Protocol Driver the entire systems is software version 1.3.1.1
24 June 2011	10122633	Addendum – Change to 2abelling and manuals, including indications for use (expand AHI range to 15 to 65). Add Printer Adapter to Model 2740 accessories.
22 November 2013	10137864	Addendum – modification of Physician Programmer Application Software from version 1.3 to 2.1 and OS Software from version 1.1 to 1.2. Updates to Physician Programmer Guide.
09 May 2014	10143400	Review for replacement of Inspire 5 Post-Market Study with Inspire 4 STAR Pivotal Trial Study to fulfil PMCF study requirements.
14 May 2015	10153332	Addendum - Addition of C5te tablet as alternative to C5 tablet for use in the Model 2740 Physician Programmer system. Addition of ferrite bead to the telemetry power supply cable. Updates to Model 2740 programmer manual.
16 October 2015	10157166	Addendum - Certificate Renewal; Change of EU Representative to HealthLink Europe Services BV, De Tweeling 20-22, 5125 MC' s-Hertogenbosch, The Netherlands.
05 November 2015	10156559	Addendum – Change shelf life from 2 to 3 years.

First Issued: **2010-10-20** Date: **2021-05-24** Expiry Date: **2024-05-26**

EC Design-Examination Certificate

Supplementary Information to CE 562872

Issued To:

Inspire Medical Systems, Inc.
5500 Wayzata Blvd, Suite 1600
Golden Valley
Minnesota
55416
USA

Date	Reference	Action
29 November 2015	10155573	Addendum - Updates to the System Implant Manual, Patient Implant Manual, and Sleep Remote Patient Manual. Introduction of new Sleep Remote Quick Guide.
20 April 2016	10160401	Addendum – Addition of Model 2500 Sleep Remote and Patient Manual. Bootloader SW Application v 1.0.0 and SW Application v 1.0.3
17 October 2016	10163529	Addendum - Substitution of the Motion C5m tablet for the C5te tablet in the Model 2740 Physician Programmer. Update of software to version 2.5.2.1
14 September 2017	8673010	Addition of electronic labelling.
03 April 2018	8651075	Addendum - Addition of Model 3028 and accessories.
14 September 2018	8902682	Addendum - Addition of Model 4340 Sensing Lead. Corrected tablet designator.
06 March 2019	7780873	Traceable to NB 0086.
13 June 2019	8958000	Addendum - Addition of Model 2740 ADLink Tablet, Manufacturing Process qualification of Model 2740 ADLink Tablet, Update of programmer software to Version 2.8.3.1
20 April 2020	3060805	Renewal; change of the address of the legal manufacturer + addition of Inc.; removal of the following devices: Inspire II Upper Airway Stimulator – Model 3024; Inspire Sensing Lead – Model 4323; the accessories in Inspire Physician Programmer - Model 2740: Tablet Connection Module and Printer adaptor (USB); Inspire Patient Programmer – Model 3032.
16 October 2020	3222102	Addendum – Dupont Tyvek Medical Packaging Transition Project for Model 4063 Inspire Stimulation Lead and Model 4340 Inspire Sensing Lead. Change name of Model 2740 from "Inspire Physician Programmer" to "Inspire Programmer".

First Issued: **2010-10-20** Date: **2021-05-24** Expiry Date: **2024-05-26**

EC Design-Examination Certificate

Supplementary Information to CE 562872

Issued To:

Inspire Medical Systems, Inc.
5500 Wayzata Blvd, Suite 1600
Golden Valley
Minnesota
55416
USA

Date	Reference	Action
14 April 2021	3254702	Amended - Model 2740 Inspire Programmer updates including new Programmer Cable with firmware Version x.1.6 and updates to Application Module tablet software to Version 3.11.3.2. Updates to the Model 2740 Inspire Programmer manual.
04 May 2021	3387814	Amended – Addition of the 2-incision technique to the Implant Manual; update to the MRI Manual to include the 2-incision implantation approach.
Current	3371947	Amended – Addition of two sterilization chambers (5 and 6) at subcontractor Steris Isomedix for the IPG Model 3028.

First Issued: **2010-10-20** Date: **2021-05-24** Expiry Date: **2024-05-26**