EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No. **CE 01942**

Issued To: **nSpire Health, Inc.**
1830 Lefthand Circle
Longmont
Colorado
80501
USA

In respect of:

The manufacture of spirometers; pulmonary function analysers; pulmonary function filters; electronic peak flow meters for spirometry; mechanical respirometers; and electronic respiratory sensors for anaesthesia and intensive care. Those aspects of Annex V related to metrology in the manufacture of peak flow meters.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Stewart Brain, Head of Compliance & Risk - Medical Devices

First Issued: **1998-06-12** Date: **2018-05-23** Expiry Date: **2023-06-11**

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By Royal Charter

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

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

Certificate No:	**CE 01942**
Date:	**2018-05-23**
Issued To:	**nSpire Health, Inc.** **1830 Lefthand Circle** **Longmont** **Colorado** **80501** **USA**

Subcontractor:	**Service(s) supplied**
nSpire Health, Ltd 8 Harforde Court John Tate Road Hertford SG13 7NW United Kingdom	**EU Representative** **Manufacture**
Parkway Products Inc. 8101 SW Frontage Road Fort Collins Colorado 80528 USA	**Manufacture**

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EC Certificate - Production Quality Assurance Certificate History

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Date: **2018-05-23**

Issued To: **nSpire Health, Inc.**
1830 Lefthand Circle
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Date	Reference Number	Action
12 June 1998		Original issue
18 January 1999		Change of Annex on certificate
31 August 1999		Change of scope
11 February 2000		Change of name
3 December 2002		Change of name and change of scope
2 May 2003		Change of scope and addition of subcontractor
27 June 2005	4676873	Change of company name and change of scope New certificate format
28 March 2007	7007223	Certificate reissue due to removal of 'Personal Diary Spirometers' from the scope Change of company name from Ferraris Respiratory, Inc to nSpire, Health, Inc
14 March 2008	7008510	Change of company address
10 June 2008	7204113	Certificate Renewal
18 July 2008	7217729	Addition of the sub-contractor Parkway Products Inc for the activity of manufacture

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Date	Reference Number	Action
24 September 2008	7273609	Changes to the list of significant sub-contractors: Removal of Piko Healthcare products (HK) Ltd; addition of Ouiko Ltd, Renzhou Administrict-Shatian Town, Dongguan, Guangdong, China for the activity of manufacture
15 July 2009	7361576	Certificate Re-issue due to change of company address of the significant sub-contractor Ouiko Ltd from 'ZRenzhou Administrict Shatian Town, Dongguan, Guangdong, China' to '4F, D Block, Jin Feng Industrial Area, Xia Jie Jiao Management District, Hu Men Town, Dong Guan City, Guangdong Province, PRC'
18 June 2013	7957171	Certificate Renewal Addition of nSpire Health, Ltd, United Kingdom as EU representative under the list of subcontractors
19 February 2015	8215986	Removal of Ouiko as a significant subcontractor Change the subcontractor 'Parkway products' address details to '8101 SW Frontage Road Fort Collins, CO 80528'

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Date	Reference Number	Action
29 January 2018	8792522	Consolidation with CE 665772 resulting in addition to scope of mechanical respirometers, electronic respiratory sensors for anaesthesia and intensive care, and peak flow meters. Addition of Manufacture to subcontractor nSpire Health Limited.
Current	8887126	Removed respiratory sensors from scope Renewal