



Certificate

Production Quality Assurance



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 and electronic peak flow meters for spirometry

on the basis of our examination under the requirements of Council Directive 93/42/EEC, Annex V, Section 3.2.

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

Gary Fenton, Global Assurance Director

First Issued: **12 Jun 1998**

Date: **24 Jun 2013**

Expiration Date: **11 Jun 2018**

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Conditions of Approval

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive. 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.

...making excellence a habit.™



List of Significant Subcontractors

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

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Subcontractor**Service(s) supplied**

nSpire Health, Ltd
Hartforde Court
John Tate Road
Hertford
SG13 7NW
United Kingdom

EU Representative

Ouiko Ltd
4F D Block Jin Feng Industrial Area
Xia Jie Jiao Management District
Hu Men Town, Dong Guan City
Guangdong Province, PRC
China

Manufacture

Parkway Products Inc
4150 Saint Cloud Drive
Loveland
Colorado
80538
USA

Manufacture

History of Quality Assurance Certificate

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Date: 18 Jun 2013
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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 Administrist-Chatian 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 Administrist 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