

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 the British Standards Institution, a Notified Body for the above Directive (Notified Body Number 0086):

David Ford, Managing Director, BSI Product Services

First Issued: 12 Jun 1998

Date: 24 Sep 2008

Expiration Date: 11 Jun 2013

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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.

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List of Significant Subcontractors

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

Certificate No. **CE 01942**
Date: **24 Sep 2008**
Issued to: **nSpire Health, Inc.**
Longmont
USA

Subcontractor

Service(s) supplied

Ouiko Ltd
Renzhou Administrict-Shatian Town
Dongguan
Guangdong
China

Manufacture

Parkway Products Inc
4150 Saint Cloud Drive
Loveland
Colorado
USA
80538

Manufacture

History of Quality Assurance Certificate

Certificate No: CE 01942
Issue Date: 24 September 2008
Issued to: nSpire Health, Inc
Longmont
USA

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
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