BSI Product Services

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26 February 2009

To whom it may concern:

I can confirm that BSI issued an EC certificate CE 01942 to nSpire Health, Inc. 1830 Lefthand Circle, Longmont, Colorado, 80501, USA in accordance with the Annex V, Section 3.2 of the Medical Device Directive 93/42/EEC. The scope of this certificate is currently, "The manufacture of spirometers, pulmonary function analysers, pulmonary function filters and electronic peak flow meters for spirometry" This certificate is maintained by BSI performing regular audits of the manufacturer's quality management system.

The following products, which the manufacturer has declared to have been manufactured under this quality system, fall within the scope of CE 01942:

Product	Classification	Product Category
1. BPd Plethysmograph	IIA	Pulmonary Function Analyzer
2. CPL(pf)	IIa	Pulmonary Function Analyzer
3. CPL	IIa	Pulmonary Function Analyzer
4. HDcpl	IIa	Pulmonary Function Analyzer
5. Eagle	IIa	Pulmonary Function Analyzer
6. HDpft3000	IIa	Pulmonary Function Analyzer
7. Owl	IIa	Pulmonary Function Analyzer
8. HDpft4000	IIa	Pulmonary Function Analyzer
9. Hawk	IIa	Pulmonary Function Analyzer
10. HDpft2000	IIa	Pulmonary Function Analyzer
11. IPL	IIa	Pulmonary Function Analyzer
12. Eaglet	IIa	Spirometry
13. HDpft1000	IIa	Spirometry
14. AccuTrax2	IIa	Spirometry
15. KoKo Spirometer	IIa	Spirometry
16. KoKo Trek Spirometer	IIa	Spirometry
17. KoKo DigiDoser	IIa	Spirometry
18. KoKoMate Office Spirometer	IIa	Spirometry
19. KoKo Moe Filters	IIa	Pulmonary Function Filters
20. DCII Filters	IIa	Pulmonary Function Filters
21. PiKo-1	IIa	Electronic Peak Flow Meter
22. PiKo-6	IIa	Electronic Peak Flow Meter
23. PiKo-1 Clinical	IIa	Electronic Peak Flow Meter

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In accordance with the Medical Devices Directive 93/42/EEC a manufacturer who fulfils the obligations imposed by Annex II is permitted to apply CE marking to a device that falls within the scope of the above-mentioned certificate.

Prior to placing the products on the market with CE marking, the manufacturer is required to make a written declaration of conformity with the above requirements for a particular product. The above products with CE marking are then permitted to be marketed in the European Union."

Yours faithfully,

Mark Adams
Project Manager / Product Technical Specialist
Healthcare