

## EC Certificate

## **Full Quality Assurance System**

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4) (Devices in Class IIa, IIb or III)

No. G1 14 11 71448 008

Manufacturer: Inspiration Healthcare Ltd

Gildor House West Street Earl Shilton

Leicestershire LE9 7EJ UNITED KINGDOM

Facility(ies): Inspiration Healthcare Ltd

Gildor House, West Street, Earl Shilton, Leicestershire LE9 7EJ,

UNITED KINGDOM

Product Nasal Continuous Positive Airway Pressure

Category(ies): devices

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 75928181

**Valid from:** 2015-02-11 **Valid until:** 2020-02-10

Date, 2015-02-10

Hans-Heiner Junker



TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

Page 1 of 1