





Product Service

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 001691 0008 Rev. 00

Manufacturer:

Inspiration Healthcare Ltd

2 Satellite Business Village

Fleming Way

Crawley, West Sussex RH10 9NE

UNITED KINGDOM

Facility(ies):

Inspiration Healthcare Ltd

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

UNITED KINGDOM

Inspiration Healthcare Ltd

2 Satellite Business Village, Fleming Way, Crawley, West Sussex

RH10 9NE, UNITED KINGDOM

Product Category(ies): Class IIa - Nasal Continuous Positive

Airway Pressure devices.

Class IIb - Heating Devices using Blankets

and Mattresses for Medical use

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.:

75946459

Valid from:

2020-01-09

Valid until:

2024-05-26

Date,

2020-01-09

Christoph Dicks

Head of Certification/Notified Body