



America

# CERTIFICATE

No. QS6 001691 0007 Rev. 00

**Certificate Holder:** **Inspiration Healthcare Ltd**  
2 Satellite Business Village  
Fleming Way  
Crawley, West Sussex RH10 9NE  
UNITED KINGDOM

**Certification Mark:**



**Scope of Certificate:** **Design and Development, Production of Airway Pressure Devices, Platforms for Stabilization / Resuscitation of the Neonate and Thermo-Regulatory Systems; Distribution and Service of Critical Care and Parenteral Feeding Equipment**

**Standard(s):** **ISO 13485:2016**

**Regulatory Authority(ies):** **Australia TGA, Health Canada, USA FDA, MHLW / PMDA.**  
**See attached for listing of specific regulatory requirements.**

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. Validity of this certificate can be obtained by visiting the website <https://www.tuev-sued.de/product-testing/certificates>

TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

**DUNS No:** **73-490-3532**

**Effective Date:** **2019-03-13**

**Expiry Date:** **2022-03-12**

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Date of Issue: 2019-03-17

( Arie Henkin )  
Manager, Certification Body MHS

TÜV SÜD America Inc. • 10 Centennial Drive Ste 207 • Peabody, MA 01960 USA • [www.tuvsud.com](http://www.tuvsud.com)

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**Regulatory Requirements: Audit/Certification Criteria**

**Australia**

- Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1

**Canada**

- Medical Device Regulations SOR/98-282, Part 1

**United States**

- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807
- 21 CFR Part 820

**Japan**

- MHLW Ministerial Ordinance 169, Article 4 to Article 68
- PMD Act

**Facility(ies):**

Inspiration Healthcare Ltd  
2 Satellite Business Village, Fleming Way, Crawley, West  
Sussex RH10 9NE, UNITED KINGDOM

Inspiration Healthcare Ltd  
Gildor House, West Street, Earl Shilton, Leicestershire LE9 7EJ,  
UNITED KINGDOM

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**Inspiration Healthcare Ltd**

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

Production, Servicing and Sales of Airway Pressure Devices,  
Platforms for Stabilization / Resuscitation of the Neonate and  
Thermo-Regulatory Systems and the Sales, Distribution and  
Service of Critical Care and Parenteral Feeding Equipment  
DUNS No: 21-556-4163



( Arie Henkin )  
Manager, Certification Body MHS

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