

Certificate US99/50618



The management system of

Respan Products Inc.

8 Erinville Drive, Erin, Ontario, N0B 1T0, Canada

has been assessed and certified as meeting the requirements of

ISO 13485:2016 EN ISO 13485:2016



For the following activities

Design, manufacture, sales and distribution of non-sterile, disposable, oxygen masks, nasal cannula, nebulizer kits, CPAP tubing, oxygen tubing and connectors, mask adaptors, aerosol masks, oxygen mask kits and respiratory breathing circuits for the area of respiratory therapy.

This certificate is valid from 11 September 2019 until 11 September 2022 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 24 August 2021
Issue 10. Certified since 11 June 1999

*Expiry date of last certificate: 31 March 2019
End date of last recertification audit: 24 August 2018*

Authorised by



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SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

HC SGS 13485 2016 0118

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The management system of

Respan Products Inc.

8 Erinville Drive,
Erin, Ontario, N0B 1T0, Canada

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex V

For the following products

Non-sterile, disposable nasal cannula, oxygen tubing, CPAP tubing, adult and paediatric face masks (including aerosol, oxygen, entrainment, high concentration and non-rebreathing), tubing connectors, mask adaptors, and nebulizer kits for usage in respiratory therapy.

Where the above scope includes class IIb or class III medical device(s), a valid EC Type Examination Certificate according to Annex III is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 11 September 2019 until 24 May 2024 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 24 August 2021
Issue 10. Certified since 11 June 1999

Certification is based on reports numbered WW/MC 09997

Authorised by

SGS United Kingdom Ltd, Notified Body 0120

202B Worle Parkway, Weston-super-Mare, BS22 6WA UK
t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

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Certificate Number US19/819943405

SGS

The quality management system of

Respan Products Inc.

8 Erinville Drive, Erin, Ontario, N0B 1T0, Canada

Dun & Bradstreet D-U-N-S identification number : 24-317-5213

has been audited against the criteria stated below and found to conform to those criteria for the scope contained in this certificate



MDSAP(ISO 13485:2016)



Canada:

Medical Devices Regulations – Part 1 SOR 98/282

United States:

21 CFR 820 / 21 CFR 803 / 21 CFR 806 / 21 CFR 807 – Subparts A to D

For the following activities and devices

Design & Manufacture of non-sterile, disposable Respiratory Products.

This certificate is valid from
Effective Date: 2019-10-03 until Expiry Date: 2022-10-02
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 2021-08-24
Issue 1. Certified since 2019-10-03

Authorised by J Hall
Business Manager

SGS United Kingdom Ltd
202B Worle Parkway, Weston-super-Mare, BS22 6WA, UK
t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

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