

SGS

Certificate US02/2804

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

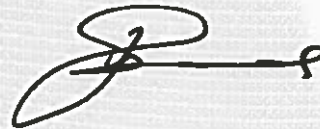
ISO 13485:2003

For the following activities

Design and manufacture of non-sterile, disposable, oxygen masks, nasal cannula, nebulizer kits, CPAP tubing, oxygen tubing and connectors and mask adaptors, aerosol masks, Medical Air Connection (MAC) System, oxygen mask kits and respiratory breathing circuits for the area of respiratory therapy.

Effective Date 01 August 2017 Expiry Date 31 December 2018
Re certification audit due before 31 December 2018
Valid subject to satisfactory surveillance audits.
Issue 11. Certified since 01 December 2002

Authorised by
Jan Saunders – Business Manager



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CMDCAS recognised registrar

SGS 13485 CMDCAS 0311

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Certificate US14/841839

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 9001:2008

For the following activities

Design, manufacture, sales and distribution of respiratory oxygen therapy products and related accessories, and components for industrial and commercial hose assemblies and related products.

This certificate is valid from 18 August 2017 until 15 September 2018
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 15 September 2018
Issue 2. Certified since 18 August 2014



Authorised by

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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 13485:2003 EN ISO 13485:2012

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 10 July 2017 until 31 March 2019
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 31 March 2019
Issue 9. Certified since 11 June 1999

Authorised by

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EC Certificate Production Quality Assurance System: Certificate US99/50617

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 10 July 2017 until 11 June 2022
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 11 June 2020

Issue 9. Certified since 11 June 1999

Certification is based on reports numbered WW/MC 09997

Authorised by

SGS United Kingdom Ltd, Notified Body 0120

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