

EC Certificate Production Quality Assurance System: Certificate US19/819943679

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 16 December 2019 until 24 May 2024
and remains valid subject to satisfactory surveillance audits.

Issue 1. Certified since 11 June 1999
and first certified by SGS Belgium NV since 16 December 2019.

Certification is based on reports numbered WW/MC/ 09997

Authorised by

SGS Belgium NV, Notified Body 1639

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SGS

Certificate Number US19/819943405

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

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SGS United Kingdom Ltd is an MDSAP authorised auditing organization

SGS MDSAP 1116

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Certificate US99/50618

SGS

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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