

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Salter Labs
30 Spur Drive
El Paso
Texas
79906
USA

Holds Certificate Number:

MD 608599

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Design, manufacture, distribution and sales of anaesthesia, respiratory and patient monitoring devices consisting of: nasal cannulas, oxygen tubings, oxygen and aerosol masks, handheld nebulizers, dry humidifiers, nebulizer compressors, oxygen analyzers, airflow and snore transducers, thermal airflow devices, pressure infusors, blood pressure cuffs, CO2 gas lines and sterile and non-sterile laryngoscopes; and associated accessories such as connectors, skin fixation products, caps, ear protectors, water traps, extensions, adapters and filters. Design, inspection, complaint handling and distribution of CPAP/BiPAP masks, endotracheal tubes, laryngeal masks and intubating stylets

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2014-01-20

Effective Date: 2018-03-05

Latest Revision Date: 2018-02-27

Expiry Date: 2021-03-04



003

Page: 1 of 2

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Location	Registered Activities
Salter Labs 30 Spur Drive El Paso Texas 79906 USA	Distribution and sales of anesthesia, respiratory and patient monitoring devices consisting of: nasal cannulas, oxygen tubings, oxygen and aerosol masks, handheld nebulizers, dry humidifiers, nebulizer compressors, oxygen analyzers, airflow and snore transducers, thermal airflow devices, pressure infusors, blood pressure cuffs, CO2 gas lines and sterile and non-sterile laryngoscopes; and associated accessories such as connectors, skin fixation products, caps, ear protectors, water traps, extensions, adapters and filters. Inspection and distribution of CPAP/BiPAP masks, endotracheal tubes, laryngeal masks and intubating stylets.
Salter Labs 2365 Camino Vida Roble Carlsbad California 92011 USA	Design of anaesthesia, respiratory and patient monitoring devices consisting of: nasal cannulas, oxygen tubings, oxygen and aerosol masks, handheld nebulizers, dry humidifiers, nebulizer compressors, oxygen analyzers, airflow and snore transducers, thermal airflow devices, pressure infusors, blood pressure cuffs, CO2 gas lines and sterile and non-sterile laryngoscopes; and associated accessories such as connectors, skin fixation products, caps, ear protectors, water traps, extensions, adapters and filters. Design and complaint handling of CPAP/BiPAP masks, endotracheal tubes, laryngeal masks and intubating stylets.
Salter Labs de Mexico S.A de C.V. Blvd. Independencia #2167 Parque Industrial Las Americas Horizonte Sur Ciudad Juarez, Chihuahua C.P. 32596 Mexico	Manufacture of anesthesia, respiratory and patient monitoring devices consisting of: nasal cannulas, oxygen tubings, oxygen and aerosol masks, handheld nebulizers, dry humidifiers, nebulizer compressors, oxygen analyzers, airflow and snore transducers, thermal airflow devices, pressure infusors, blood pressure cuffs, CO2 gas lines; and associated accessories such as connectors, skin fixation products, caps, ear protectors, water traps, extensions, adapters and filters.
Salter Labs 2460 Coral Street Vista California 92081 USA	Design, manufacture and distribution of sterile and non-sterile laryngoscope devices and related accessories.

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Page: 2 of 2

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