



Certificate of Registration

OUALITY 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 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 distribution of CPAP/BiPAP masks, endotracheal tubes, laryngeal masks and intubating stylets.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2014-01-20 Effective Date: 2021-03-05 Latest Revision Date: 2021-09-03 Expiry Date: 2024-03-04

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Certificate No: MD 608599

Location

Salter Labs 30 Spur Drive El Paso Texas 79906 USA

Registered Activities

Design, manufacture, distribution 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 distribution 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 CP 32596 Mexico Manufacture 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, non-sterile laryngoscopes; and associated accessories such as connectors, skin fixation products, caps, ear protectors, water traps, extensions, adapters and filters.



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