



## EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No.

CE 608598

Issued To:

Salter Labs

100 W. Sycamore Road

Arvin California 93203 USA

In respect of:

Design and manufacture of nasal cannulas, oxygen tubings, oxygen and aerosol masks, handheld nebulizers, dry humidifiers, nebulizer compressors, pressure infusors, and water traps.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Frank Lee, EMEA Compliance & Risk Director

First Issued: 20 January 2014

Date: 17 February 2017

Expiry Date: 20 February 2022

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MKS 8PP. Tel: + 44 345 080 9000 BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK. A member of RSI Group of Companies.





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Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

### List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

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#### Subcontractor:

Service(s) supplied

MT Promedt Consulting GmbH

Altenhofstrasse 80 66386 St. Ingbert

Germany

**EU Representative** 

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

Salter Labs

2365 Camino Vida Roble

Carlsbad

California 92011

USA

Design

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# EC Certificate - Full Quality Assurance System Certificate History

Certificate No:

CE 608598

Date:

17 February 2017

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Arvin California 93203 USA

Date	Reference Number	Action
20 January 2014	8083132	Initial issue, transfer from MEDCERT certificate number: 1186GB410130715
25 June 2014	8180007	Change of sub contractor name From Salter Labs de Mexico. Blvd. Independencia # 2167, Parque Industrial Las Americas, Ciudad Juarez, 32700 Chihuahua, MEXICO To 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
10 November 2015	8363832	Extension to scope to include pressure infusors.
17 February 2017	8555074	Renewal. Change to scope to remove "spirometers, oxygen analyzers, airflow and snore transducers, thermal airflow devices accessories and filters".

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This certificate was issued electronically and is bound by the conditions of the contract.