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By Royal Charter

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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EC Certificate - Full Quality Assurance System

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:

Certificate No:	**CE 608598**
Date:	**17 February 2017**
Issued To:	**Salter Labs** **100 W. Sycamore Road** **Arvin** **California** **93203** **USA**

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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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".