

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
30 Spur Drive
El Paso
Texas
79906
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 2797):



Albert Roossien, Regulatory Lead

First Issued: **2014-01-20**

Date: **2019-02-15**

Expiry Date: **2022-02-20**

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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.

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

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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 2365 Camino Vida Roble Carlsbad California 92011 USA	Design
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

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EC Certificate - Full Quality Assurance System Certificate History

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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".
6 July 2017	8749657	Change of address of legal manufacturer from 100 W. Sycamore Road, Arvin, California, 93203, USA to 30 Spur Drive, El Paso, Texas 79906, USA. Remove 30 Spur Drive, El Paso, Texas 79906, USA address from list of subcontractors.
Current	8750146	Traceable to NB 0086.