EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 738597 R000

Manufacturer: Salter Labs

Address:
30 Spur Drive
El Paso
Texas
79906
USA

Single Registration Number: US-MF-000007934

EU Authorised Representative: MT Promedt Consulting GmbH

Address:
Altenhofstrasse 80
66386 St. Ingbert
Germany

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III and Class IIb implantable devices an Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2022-09-09**

Current Issue Date: **2022-09-09**

Starting Validity Date: **2022-09-09**

Expiry Date: **2027-09-08**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
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Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Air/Oxygen Masks	IIa
Air/Oxygen Cannulas	IIa
Aerosol Masks	IIa
Oxygen Administration Tubing, Connectors, and Water Traps	IIa
Cold Nebulizing Systems	IIa
Humidifying Systems, Oxygen Administration	IIa
Vital Signs Telemetry Instruments - consumables (ETCO2 Cannulas)	IIa
Vital Signs Telemetry Instruments - consumables (ETCO2 Masks)	IIa
InfuseIT Pressure Infusors / Pressure Infusor Bag	IIa

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	3316763	Issued

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List of Critical Subcontractors and Crucial Suppliers

Recognised as being involved in services related to the products covered by:

MDR 738597 R000

Date: **2022-09-09**

Critical Subcontractor/Crucial Supplier	Service(s) supplied
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**
SunMed LLC 2710 Northridge Dr NW Suite A Grand Rapids Michigan 49544 USA	**Design**

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