



DECLARATION OF CONFORMITY
DOC-20015a Humidifiers

Salter Labs
30 Spur Drive
El Paso, TX 79906 USA

SRN: US-MF-000007934

Basic UDI: 006074TF1008_HumidifierWK

Product Name:
Intended Purpose:

Humidifiers

The bubble humidifier is intended to add moisture to breathing gases for administration to patients in homecare, hospital, extended care, and hospice.

Model Number or Designator:

See the following table of part numbers

Control Designator:

DOC-20015a 12-Sept-2022

Device Classification:

Class IIa, Rule 2, according to the (EU) MDR 2017/745, Annex VIII; Chapter I short-term use; Chapter III, Rule 2 non/invasive channeling gases

Conformity Route:

Route of conformity is according to (EU) MDR Annex IX Quality Management System

EMDN Nomenclature code (EMDN)

R060202, Humidifying System, oxygen administration

Global Medical Device Nomenclature Code (GMDN)

35113, Non-Heated Inspiratory Line Humidifier

Universal Medical Device Nomenclature System (UMDNS)

12051, Humidifiers, Non-Heated

Product Options/Accessories:

N/A

EC Certificate—Full Quality Assurance System

MDR 738597

Expiry Date: 09 Sep-2027

Notified Body:

BSI Group Inc.,
Notified Body CE 2797
Say Building
John M. Keynesplein 9
1066 EP Amsterdam
Netherlands
www.bsigroup.com

Authorized EU Representative:

MT Promedt Consulting GmbH
Altenhofstasse 80
D-66386 St. Ingbert
Germany

Revision: 1



Authorized Signature and Function
Printed Name: Rob Yamashita,
Vice President Regulatory

Date of Issue: 12-Sept-2022
Place of Issue: Regulatory Office, SunMed
Grand Rapids, Michigan, USA

This declaration of conformity is issued under the sole responsibility of SunMed. We hereby declare that the medical device(s) specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices.

All technical documentation is retained at the premises of the manufacturer/technical documentation location.



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UDI	Model # /Case Qty	Product Description
00607411700002 10607411700009	7100-0 7100-0-50	Bubble Humidifier with 3 PSI safety valve
00607411700040 10607411700047	7600-0 7600-0-50	Bubble Humidifier with 6 PSI safety valve
00607411700057 10607411700054 20607411700051	7900-0-0 7900-0-10 7900-0-25	Bubble Humidifier (6-15 LPM) with 6 PSI (410 mbars) safety valve
00607411102080 10607411102087	7907-7-0 7907-7-10	High flow oxygen therapy kit. This kit contains: (1) - # 1600HF Adult Nasal Cannula, 7' Tube (1) - # 7900 Bubble Humidifier, 6 psi
00607411893476 10607411700085	7907TLC-7 7907TLC-7-25	High Flow Oxygen Therapy Kit. This kit contains: (1) - #1600HFTLC-7 Nasal (Adult) High Flow TLCannula™. (1) - #7900 Bubble Humidifier (high flow)
00607411102738 10607411102735	7914-14 7914-14-10	High flow oxygen therapy kit. This kit contains: (1) - # 1600HF-14 Adult Nasal Cannula, 14' Tube (1) - # 7900 Bubble Humidifier, 6 psi
00607411893483 10607411893480	7914TLC-14-0 7914TLC-14-25	High Flow Oxygen Therapy Kit This kit contains:-(1) - #1600HFTLC- 14 Nasal (Adult) High Flow TLCannula™. (1) - #7900 Bubble Humidifier (high flow)
00607411102066 10607411102063	7925-25 7925-25-10	High Flow Oxygen Therapy Kit This kit contains:-(1) - #1600HFTLC- 25 Nasal (Adult) High Flow TLCannula™. (1) - #7900 Bubble Humidifier (high flow)
00607411951046 10607411007122	E7100-0 E7100-0-50	Bubble Humidifier with 3 PSI safety valve
00607411 006593 10607411006590	E7600-0 E7600-0-50	Bubble Humidifier with 6 PSI safety valve
00607411000898 10607411000895 20607411000892	E7900-0 E7900-0-10 E7900-0-25	Bubble Humidifier (6-15 LPM) with 6 PSI (410 mbars) safety valve
00607411200915 10607411200912	L7600-0 L7600-50	Bubble Humidifier with 6 PSI safety valve
00607411888922 10607411888929	M5120-0 M5120-50	Bubble Humidifier with 3 PSI safety valve
00607411920097 10607411920094	NP7100-0-0 NP7100-0-50	Bubble Humidifier with 3 PSI safety valve
00607411920103 10607411920100	NP7600-0 NP7600-0-50	Bubble Humidifier with 6 PSI safety valve