



DECLARATION OF CONFORMITY

TF1008 Humidifiers

Salter Labs
30 Spur Drive
El Paso, Texas, 79906
USA

Product Name: Humidifiers and Accessories
Model Number or Designator: See attached
Control Designator: TF1008 22-August-2017
Device Classification: Class IIa, Rule 2, per Annex IX of the European Medical Device Directive (93/42/EEC)
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

The object of the declaration described is in conformity with the provisions of Council Directive: 93/42/EEC (Medical Devices Directive), Annex II 3.2., as amended by 2007/47/EC.

The Manufacturer is certified by the Notified Body listed below to EN ISO 13485:2012 and Annex II excluding section four (4) of the Medical Device Directive.

EC Certificate Number: CE 608598. Expiry Date: 20 February 2022

Notified Body: BSI Group
Kitemark Court, Davy Avenue
Knowlhill, Milton Keynes
MK5 8 PP
United Kingdom.

Authorized EU Representative: MT Promedt Consulting GmbH
Altenhofstrasse 80
66386 St. Ingbert
Germany

Revision: G

Handwritten signature of Peggy Collins

Signature: \_\_\_\_\_
Printed Name: Peggy Collins
Title: Regulatory Affairs

Date of Issue: 22-August-2017
Place of Issue: Regulatory Office, Salter Labs
Carlsbad, CA.



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El Paso, Texas, 79906  
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<b>Model #</b>	<b>Product Description</b>
7100-0	Bubble Humidifier with 3 PSI safety valve – 50/cs
7600-0	Bubble Humidifier with 6 PSI safety valve – 50/cs
7900-0	Bubble Humidifier (6-15 LPM) with 6 PSI (410 mbars) safety valve 10/c
AR-7600-0	Bubble Humidifier with 6 PSI safety valve – 50/cs
E7100-0	Bubble Humidifier with 3 PSI safety valve – 50/cs
E7600-0	Bubble Humidifier with 6 PSI safety valve – 50/cs
E7900-0	Bubble Humidifier (6-15 LPM) with 6 PSI (410 mbars) safety valve – 10/cs
L7600-0	Bubble Humidifier with 6 PSI safety valve – 50/cs
M5120	Bubble Humidifier with 3 PSI safety valve
M7600	Bubble Humidifier with 6 PSI safety valve

**Humidifier Accessories**

<b>Model #</b>	<b>Product Description</b>
SO-676	Humidifier tubing, oxygen, 3-channel 15" w/male thread grip and ribbed connector
SO-1790	Humidifier tubing, oxygen, 3 channel 21" w/male thread grip and ribbed connector