



DECLARATION OF CONFORMITY
DOC-20013d Nebulizers

Salter Labs
30 Spur Drive
El Paso, Texas 79906
USA

SRN:US-MF-000007934

Basic UDI: 006074TF1007_NebulizerYE

Product Name:
Intended Purpose

Model Number or Designator:
Control Designator:

Device Classification:

Conformity Route

EMDN Nomenclature Code (EMDN):
Global Medical Device Nomenclature Code (GMDN):
Universal Medical Device Nomenclature System (UMDNS):
Product Options/Accessories:
EC Certificate Number Full Quality Assurance System

Notified Body:

Authorized EU Representative:

Revision: **1**



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

Nebulizers

The Nebulizer is intended for use where liquids (solutions, suspensions, and emulsions) medications are to be delivered to a patient in aerosol form.

See the following table of part numbers

DOC-20013d 12-Sept-2022

Class IIa, Rule 20, According to the (EU) MDR 2017/745, Annex VIII, Chapter I, short-term use; Chapter III Rule 20: Nebulizers are invasive devices which are intended to administer medicinal products by inhalation and are classified as Class IIa.

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

R060101, Cold nebulizing system

35457, Nebulizing System, Non-Heated

12712, Nebulizers

N/A

MDR 738597

Expiry Date: 09-Sept-2027

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

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

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.



DECLARATION OF CONFORMITY
DOC-20013d Nebulizers

Salter Labs
30 Spur Drive
El Paso, Texas 79906
USA

SRN:US-MF-000007934

Basic UDI: 006074TF1007_NebulizerYE

UDI #	Model Number /Case Qty	Description
00607411001017 10607411001014	1003-0 1003-0-50	Mouth Piece Standard 22mm
00607411919299 10607411919296	13500 13500-10	NebuTech HDN Nebulizer with inhalation and exhalation valve, mouthpiece. 7' (2.1 m) supply tube and 1 female thread grip connector.
00607411919312 10607411919319	13505 13505-10	NebuTech HDN Nebulizer with inhalation valve, universal mask adaptor, mouthpiece, 7' (2.1 m) supply tube and female thread grip connector.
00607411919329 10607411919326	13506 13506-10	NebuTech HDN Nebulizer with inhalation 7' (2.1 m) supply tube, female thread grip connector, adult aerosol mask, elastic strap fixation, mouthpiece with valve
00607411919343 30607411919344	13950 13950-50	Full KIT Nebulizer set: mouthpiece, tee adaptor, reservoir, 7' (2.1 m) supply tube
00607411919350 30607411919351	13951 13951-50	Full KIT Nebulizer Set with mouthpiece, tee adaptor, reservoir, 7' (2.1 m) supply tube, female thread grip connector.
00607411919367 30607411919368	13952 13952-50	Full Kit Nebulizer Set with mouthpiece, tee adaptor, reservoir, 7' (2.1 m) supply tube, female thread grip connector
00607411919381 30607411919382	13956 13956-50	Nebulizer
30607411919399	13957-50	Mouthpiece (22 mm)
00607411919404 30607411919405	13960 13960-50	Nebulizer (Adult) with aerosol mask, 7' (2.1 m) supply tube, over-the-ear fixation and one female thread grip connector.
00607411919411 30607411919412	13962 13962-50	Nebulizer (Adult), with aerosol mask, 7' (2.1 m) supply tube, female thread grip connector, elastic strap fixation.
00607411919428 30607411919429	13963 13963-50	Nebulizer (Pediatric) with aerosol mask, 7' (2.1 m) supply tube, elastic strap fixation and one female thread grip connector.
00607411860058 10607411860055	8685-0 8685-0-1	Filter Media, for use with Salter exhalation filter. Contains 30 filters
00607411000737 10607411000734	8900-14 8900-14-25	Nebulizer, anti-drool "T", mouthpiece, 6" reservoir tube, 14' tube
00607411890031 10607411890038	8900-7 8900-7-50	Full Kit Nebulizer Set with mouthpiece, tee adaptor, reservoir, 7' (2.1 m) supply tube
00607411005695 10607411005692	8900-8 8900-8-50	Nebulizer with tee adaptor, Mouthpiece and reservoir tube, 8' (2.4 m) tubing
00607411890055 10607411890052	8900TG-7 8900TG-7-50	Full Kit Nebulizer Set with mouthpiece, tee adaptor, reservoir, 7' (2.1 m) supply tube, female thread grip connector.
00607411890062 10607411890069	8901-0 8901-0-50	Nebulizer Single patient use. Do not sterilize
00607411890079 10607411890076	8902-7 8902-7-50	Nebulizer with 7' (2.1 m) supply tube
00607411890086 10607411890083	8903-0 8903-0-50	Nebulizer with adult size Over-the-ear Style Under-the-chin fit aerosol mask, (vinyl)
00607411890123 10607411890120	8906-7 8906-7-50	Nebulizer (Pediatric) with aerosol mask, 7' (2.1 m) supply tube, elastic strap fixation.



Salter Labs
30 Spur Drive
El Paso, Texas 79906
USA

DECLARATION OF CONFORMITY
DOC-20013d Nebulizers

SRN:US-MF-000007934

Basic UDI: 006074TF1007_NebulizerYE

UDI #	Model Number /Case Qty	Description
00607411890130 10607411890137	8906TG-7 8906TG-7-50	Nebulizer (Pediatric) with aerosol mask, 7' (2.1 m) supply tube, elastic strap fixation with female thread grip connector.
00607411890147 10607411890144	8910-0 8910-0-50	Nebulizer Tee Adaptor, Anti-drool 22 mm (I.D.) x 22 mm (O.D.) x 18 mm (I.D.), for use with Salter Labs® Nebulizers.
00607411890154 10607411890151	8911-7 8911-7-50	Nebulizer Set with mouthpiece, tee adaptor, 7' (2.1 m) supply tube
00607411890178 10607411890175	8912-0 8912-7-50	Nebulizer Set with mouthpiece, tee adaptor, reservoir
00607411890185 10607411890182	8913-0 8913-0-50	Nebulizer Set with mouthpiece, tee adaptor
00607411890208 10607411890205	8915-7 8915-7-50	In-Line Nebulizer Set with Tee adaptor (22 mm O.D. x 22 mm O.D. x 18 mm I.D.), reservoir, 7' (2.1 m) supply tube.
00607411890239 10607411890236	8917-0 8917-0-50	Aerosol Tee Adaptor, 22 mm O.D. x 22 mm O.D. x 15 mm I.D.
00607411890253 10607411890250	8924-7 8924-7-50	Nebulizer (Adult) with aerosol mask, 7' (2.1 m) supply tube, elastic strap fixation.
00607411890260 10607411890267	8924TG-7 8924TG-7-50	Nebulizer (Adult), with aerosol mask, 7' (2.1 m) supply tube, female thread grip connector, elastic strap fixation.
00607411891816 10607411891813	8927-7 8927-7-50	Nebulizer with Adult I-Guard™ Mask – Aerosol delivery system (vinyl) with 7' (2.1 m) supply tube
00607411890277	8945-7	Nebulizer kit w/ Medication Port. T-Adaptor, Oxygen Tubing 7" (2.1 m).
00607411099595	8955-7-25	NEBULIZER KIT for continuous medication delivery- This kit contains: (1) - #8945 In line Nebulizer Kit ; (1) - # 8949, Fluid Administration Set.
00607411918063	8975-0-50	Replacement Mask Adapter: for use with Salter Labs Aerosol Face Mask 8960
00607411890550 10607411890557 20607411890554	8980-0 8980-0-10 8980-0-25	Exhalation Aerosol Filter For use with NebuTech® HDN® Nebulizer
00607411976285 10607411976282	8995-0 8995-0-50	NebuTech Expiratory Bacterial/Viral Filter

