



Salter Labs
30 Spur Drive
El Paso, Texas 79906
USA

DECLARATION OF CONFORMITY
DOC-20013d Nebulizers

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

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

Notified Body:

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

Authorized EU Representative:

MT Promedt Consulting GmbH
Ernst-Heckel-Straße 7
66386 St. Ingbert
Germany

Revision: **1**

Authorized Signature and Function
Title: Regulatory Affairs
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.



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

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, inhalation-exhalation valve, mouthpiece, 7' (2.1 m) supply tube, 1 female thread grip connector.
00607411919312 10607411919319	13505 13505-10	NebuTech HDN Nebulizer, inhalation valve, mouthpiece, 7' (2.1 m) supply tube, female thread grip connector
00607411919329 10607411919326	13506 13506-10	NebuTech HDN Nebulizer, Aerosol Mask (Adult), valve mouthpiece, 7' (2.1 m) supply tube, female thread grip connector
00607411919343 30607411919344	13950 13950-50	Nebulizer Kit: mouthpiece, T-adaptor, reservoir, 7' (2.1 m) supply tube
00607411919350 30607411919351	13951 13951-50	Nebulizer Kit, mouthpiece, T-adaptor, reservoir, 7' (2.1 m) supply tube, female thread grip connector
00607411919367 30607411919368	13952 13952-50	Nebulizer Kit, mouthpiece, T-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), aerosol mask, 7' (2.1 m) supply tube, female thread grip connector
00607411919411 30607411919412	13962 13962-50	Nebulizer (Adult), aerosol mask, 7' (2.1 m) supply tube, female thread grip connector
00607411919428 30607411919429	13963 13963-50	Nebulizer (Pediatric), aerosol mask, 7' (2.1 m) supply tube, female thread grip connector
00607411860058 10607411860055	8685-0 8685-0-1	Filter Media, Salter exhalation filter
00607411000737 10607411000734	8900-14 8900-14-25	Nebulizer, anti-drool "T", mouthpiece, 6" reservoir tube, 14' supply tube
00607411890031 10607411890038	8900-7 8900-7-50	Full Kit Nebulizer Set with mouthpiece, t-adaptor, reservoir, 7' (2.1 m) supply tube
00607411005695 10607411005692	8900-8 8900-8-50	Nebulizer with t-adaptor, mouthpiece, reservoir tube, 8' (2.4 m) tubing
00607411890055 10607411890052	8900TG-7 8900TG-7-50	Nebulizer Kit, mouthpiece, T-adaptor, reservoir, 7' (2.1 m) supply tube, female thread grip connector.
00607411890062 10607411890069	8901-0 8901-0-50	Nebulizer
00607411890079 10607411890076	8902-7 8902-7-50	Nebulizer, 7' (2.1 m) supply tube
00607411890086	8903-0	Nebulizer, Aerosol Mask (adult)



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10607411890083	8903-0-50	
00607411102028 10607411102025	8904-7 8904-7-50	Nebulizer, Aerosol mask (adult), 7' (2.1 m) supply tube
00607411890116 10607411890113	8905-0 8905-0-50	Nebulizer, Aerosol mask (Pediatric)
00607411890123 10607411890120	8906-7 8906-7-50	Nebulizer, Aerosol mask (Pediatric), 7' (2.1 m) supply tube
00607411890130 10607411890137	8906TG-7 8906TG-7-50	Nebulizer, Aerosol mask (Pediatric), 7' (2.1 m) supply tube, female thread grip connector
00607411890147 10607411890144	8910-0 8910-0-50	Nebulizer T-Adaptor, anti-drool, 22 mm (I.D.) x 22 mm (O.D.) x 18 mm (I.D.)
00607411890154 10607411890151	8911-7 8911-7-50	Nebulizer Set, mouthpiece, T-adaptor, 7' (2.1 m) supply tube
00607411890178 10607411890175	8912-0 8912-7-50	Nebulizer Set, mouthpiece, T-adaptor, reservoir
00607411890185 10607411890182	8913-0 8913-0-50	Nebulizer Set, mouthpiece, T-adaptor
00607411890208 10607411890205	8915-7 8915-7-50	In-Line Nebulizer Set, T-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 T-Adaptor, 22 mm O.D. x 22 mm O.D. x 15 mm I.D.
00607411890253 10607411890250	8924-7 8924-7-50	Nebulizer, Aerosol mask (Adult), 7' (2.1 m) supply tube
00607411890260 10607411890267	8924TG-7 8924TG-7-50	Nebulizer, Aerosol mask (Adult), 7' (2.1 m) supply tube, female thread grip connector
00607411891816 10607411891813	8927-7 8927-7-50	Nebulizer, I-Guard Mask (Adult), 7' (2.1 m) supply tube
00607411890406 20607411894064	8936-7 8936-7-25	Nebulizer, Aerosol mask (Pediatric), 7' (2.1 m) supply tube
00607411890277	8945-7	Nebulizer kit, medication port, T-adaptor, 7' (2.1 m) supply tube
00607411099595	8955-7-25	Nebulizer kit, (1) #8945 In line Nebulizer Kit, (1) # 8949, fluid administration set
00607411918063	8975-0-50	Replacement Mask Adapter, for #8960 Aerosol Face Mask
00607411890550 10607411890557 20607411890554	8980-0 8980-0-10 8980-0-25	NebuTech Exhalation Aerosol Filter
00607411976285 10607411976282	8995-0 8995-0-50	NebuTech Expiratory Bacterial/Viral Filter