



**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

**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  
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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.



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



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|----------------------------------------------------|----------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------|
| 00607411890130<br>10607411890137                   | 8906TG-7<br>8906TG-7-50          | Nebulizer (Pediatric) with aerosol mask, 7' (2.1 m) supply tube, elastic strap fixation with female thread grip connector.                       |
| 00607411890147<br>10607411890144                   | 8910-0<br>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<br>10607411890151                   | 8911-7<br>8911-7-50              | Nebulizer Set with mouthpiece, tee adaptor, 7' (2.1 m) supply tube                                                                               |
| 00607411890178<br>10607411890175                   | 8912-0<br>8912-7-50              | Nebulizer Set with mouthpiece, tee adaptor, reservoir                                                                                            |
| 00607411890185<br>10607411890182                   | 8913-0<br>8913-0-50              | Nebulizer Set with mouthpiece, tee adaptor                                                                                                       |
| 00607411890208<br>10607411890205                   | 8915-7<br>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<br>10607411890236                   | 8917-0<br>8917-0-50              | Aerosol Tee Adaptor, 22 mm O.D. x 22 mm O.D. x 15 mm I.D.                                                                                        |
| 00607411890253<br>10607411890250                   | 8924-7<br>8924-7-50              | Nebulizer (Adult) with aerosol mask, 7' (2.1 m) supply tube, elastic strap fixation.                                                             |
| 00607411890260<br>10607411890267                   | 8924TG-7<br>8924TG-7-50          | Nebulizer (Adult), with aerosol mask, 7' (2.1 m) supply tube, female thread grip connector, elastic strap fixation.                              |
| 00607411891816<br>10607411891813                   | 8927-7<br>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<br>10607411890557<br>20607411890554 | 8980-0<br>8980-0-10<br>8980-0-25 | Exhalation Aerosol Filter For use with NebuTech® HDN® Nebulizer                                                                                  |
| 00607411976285<br>10607411976282                   | 8995-0<br>8995-0-50              | NebuTech Expiratory Bacterial/Viral Filter                                                                                                       |

