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|---|---|
| Legal Manufacturer | Vyairé Medical, Inc. - 26125 North Riverwoods Blvd., Mettawa, IL 60045, USA |
| Product | Nebulizers |
| Product Codes | See Attachment |
| GMDN Codes | See attachment |
| EC Representative | Emergo Europe - Prinsessegracht 20, 2514 AP The Hague, The Netherlands |
| We, the manufacturer hereby declare under sole responsibility that the products listed in this document are in conformity with the Essential Requirements of Annex I and meets the provisions of Council Directive 93/42/EEC, as amended by 2007/47/EC for medical devices. The medical devices are manufactured under control of ISO 13485:2016 Quality Management System. | |
| General applicable directives: | Medical Device Directive: Council Directive 93/42/EEC of 14 June, 1993 as amended, concerning medical devices |
| Notified Body | BSI Group The Netherlands B.V. - Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands |
| EC Certificate(s) | CE 703694 |
| Annex | II, excluding Section 4 |
| Quality System Certificate | FM 549042 MDSAP 681543 |
| Full Quality System | ISO 13485:2016 |
| Other applicable directive | N/A |


 Regulatory Affairs VP/Director or Designee
 Colleen Watson

6 DEC 2019
 Date and Place
 26125 N. Riverwoods Blvd.
 Mettawa, IL 60045 USA


 QA Manufacturing Site Representative
 Indra Montoya

5 Dec 19
 Date and Place
 Cerrada Vía de la Producción No. 85
 PIMSA III, Mexicali, B.C. México


 OEM Quality Designee
 Ilkka Lehmusvirta

05-DEC-2019
 Date and Place
 Kuortaneenkatu 2,
 FI-00510, Helsinki, Finland

Attachment

Product Device Listing

| Product Number | Description | EU Class | Class Rule | GMDN Code | Type of CE Marking | Technical File |
|----------------|---|----------|------------|-----------|--------------------|----------------|
| 002002 | Nebulizer with Air Entrainment | Ila | 2 | 35457 | CE 2797 | RT-05 |
| 002430 | Airlife™ Misty Max 10™ Nebulizer | Ila | 2 | 35457 | CE 2797 | RT-05 |
| 002431 | Airlife™ Misty Max 10™ Nebulizer with 7' (2.1 m) Crush Resistant Oxygen Tubing | Ila | 2 | 35457 | CE 2797 | RT-05 |
| 002433 | Airlife™ Misty Max 10™ Nebulizer with 7' (2.1 m) Crush Resistant Oxygen Tubing and Adult Aerosol Mask | Ila | 2 | 35457 | CE 2797 | RT-05 |
| 002434 | Airlife™ Misty Max 10™ Nebulizer with 7' (2.1 m) Crush Resistant Oxygen Tubing, Baffled Tee Adapter and Mouthpiece | Ila | 2 | 35457 | CE 2797 | RT-05 |
| 002435 | Airlife™ Misty Max 10™ Nebulizer with 7' (2.1 m) Crush Resistant Oxygen Tubing, Tee Adapter (22 mm I.D./22 mm O.D.) and Mouthpiece | Ila | 2 | 35457 | CE 2797 | RT-05 |
| 002438 | Airlife™ Misty Max 10™ Nebulizer with 7' (2.1 m) Crush Resistant Oxygen Tubing, Baffled Tee Adapter, Mouthpiece and 6" (15 cm) Flextube | Ila | 2 | 35457 | CE 2797 | RT-05 |
| 002443 | Airlife™ Misty Max 10™ Nebulizer with Pediatric Aerosol Mask (Under-the-Chin Style) | Ila | 2 | 35457 | CE 2797 | RT-05 |
| 002444 | Airlife™ Misty Max 10™ Nebulizer with 7' (2.1 m) Crush Resistant Oxygen Tubing and Pediatric Aerosol Mask (Under-the-Chin Style) | Ila | 2 | 35457 | CE 2797 | RT-05 |
| 002446 | Airlife™ Misty Max 10™ Nebulizer with 2.1 m (7') Female U/Connect-It™ Crush | Ila | 2 | 35457 | CE 2797 | RT-05 |

Once completed, this document is considered a record that must be stored in accordance with company procedures.

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|--------|--|-----|---|-------|---------|-------|
| | Resistant Oxygen Tubing, Baffled Tee Adapter, Mouthpiece and 15 cm (6") Flextube | | | | | |
| 002450 | Airlife™ Misty Max 10™ Nebulizer, Medication System with Filter | Ila | 2 | 35457 | CE 2797 | RT-05 |
| 002501 | Airlife™ Misty Finity™ Direct Connect Large Volume Continuous Nebulizer | Ila | 2 | 35457 | CE 2797 | RT-05 |
| 002502 | Airlife™ Misty Finity™ Direct Connect Large Volume Continuous Nebulizer with Adult Aerosol Mask and 2.4 m/15 cm (8'/6") Segmented Clear Aerosol Tubing | Ila | 2 | 35457 | CE 2797 | RT-05 |
| 002530 | Airlife™ Misty Finity™ Medium Volume Low Flow Continuous Nebulizer with 2.1 m (7') Crush Resistant Oxygen Tubing | Ila | 2 | 35457 | CE 2797 | RT-05 |
| 002533 | Airlife™ Misty Finity™ Medium Volume High Flow Continuous Nebulizer with 2.1 m (7') Crush Resistant Oxygen Tubing | Ila | 2 | 35457 | CE 2797 | RT-05 |
| 002534 | Airlife™ Misty Finity™ Medium Volume High Flow Continuous Nebulizer with 2.1 m (7') Crush Resistant Oxygen Tubing and Adult Aerosol Mask | Ila | 2 | 35457 | CE 2797 | RT-05 |
| FN2431 | Fast Neb, 7' Tubing | Ila | 2 | 35457 | CE 2797 | RT-05 |
| FN2433 | Fast Neb with Adult Aerosol Mask, 84" Tubing | Ila | 2 | 35457 | CE 2797 | RT-05 |
| FN2434 | Fast Neb, Swivel Baffled Mouth Tee, 7' Tubing | Ila | 2 | 35457 | CE 2797 | RT-05 |
| FN2438 | Fast Neb w/Tee Adapter, 84" Tubing | Ila | 2 | 35457 | CE 2797 | RT-05 |
| FN2439 | Fast Neb, Swivel Baffled Mouth Tee, 14' Tubing, 6" FlexTube | Ila | 2 | 35457 | CE 2797 | RT-05 |
| FN2444 | Fast Neb, Pediatric Mask, 7' Tubing | Ila | 2 | 35457 | CE 2797 | RT-05 |
| FN2445 | Fast Neb, Swivel Baffled Mouth Tee, 7' U-Connect-It Tubing | Ila | 2 | 35457 | CE 2797 | RT-05 |

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| FN2446 | Fast Neb, Swivel Baffled Mouth Tee, 7' U-Connect-It Tubing, 6" FlexTube | Ila | 2 | 35457 | CE 2797 | RT-05 |
| FN2455 | Fast Neb, Ped Elephant Mask, 7' Tubing | Ila | 2 | 35457 | CE 2797 | RT-05 |
| 001503 | AirLife™ Tee Adapter 22mm O.D. Arms, 18mm Base Designed for use with Small Nebulizers | Ila | 2 | 35457 | CE 2797 | RT-05 |
| 001505 | AirLife™ Tee Adapter With One Arm 22mm I.D., One Arm 22mm O.D., 18mm I.D. Base with Mouthpiece | Ila | 2 | 35457 | CE 2797 | RT-05 |
| 001506 | AirLife™ Tee Adapter and Universal Mouthpiece With 22mm O.D. Arms, 18mm Base Designed for Use with Small Nebulizers | Ila | 2 | 35457 | CE 2797 | RT-05 |
| 001508 | AirLife™ "Baffled" Tee Adapter 22mm O.D. Arms, 18mm Base Designed for use with Small Nebulizers | Ila | 2 | 35457 | CE 2797 | RT-05 |
| 002060 | AirLife™ Tee Adapter with Valve, 22mm O.D./O.D. ISO Connections | Ila | 2 | 35457 | CE 2797 | RT-05 |
| 002061 | AirLife™ Tee Adapter with Valve, 22mm O.D. x 22mm I.D. ISO Connections | Ila | 2 | 35457 | CE 2797 | RT-05 |
| 002437 | AirLife™ Misty Max 10" Nebulizer with Baffled Tee Adapter and Mouthpiece | Ila | 2 | 35457 | CE 2797 | RT-05 |
| 002439 | AirLife™ Misty Max 10™ Nebulizer with 14' (4.2m) Crush Resistant Oxygen Tubing, Baffled Tee Adapter, Mouthpiece, and 6" (15cm) Flextube | Ila | 2 | 35457 | CE 2797 | RT-05 |
| 002442 | AirLife™ Misty Max 10™ Nebulizer with 7' (2.1m) Crush Resistant Oxygen Tubing, Tee Adapter, Intermittent Flow Control Valve, and Mouthpiece | Ila | 2 | 35457 | CE 2797 | RT-05 |

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| 002445 | "AirLife™ Misty Max 10™ Nebulizer with 7' (2.1m) Female U/Connect-It Crush Resistant Oxygen Tubing, Baffled Tee Adapter, and Mouthpiece" | Ila | 2 | 35457 | CE 2797 | RT-05 |
| 002458 | AirLife™ Brand Misty Max 10™ Nebulizer with 7' (2.1m) Crush Resistant Oxygen Tubing and Angled Mouthpiece | Ila | 2 | 35457 | CE 2797 | RT-05 |
| 002432 | AirLife™ Misty Max 10" Nebulizer with Adult Aerosol Mask | Ila | 2 | 35457 | CE 2797 | RT-05 |

| GMDN Code | GMDN Term |
|-----------|-------------------------------|
| 35457 | Nebulizing system, non-heated |