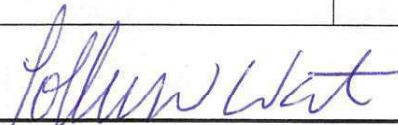


Legal Manufacturer	Vyaire Medical, Inc. - 26125 North Riverwoods Blvd., Mettawa, IL 60045, USA
Product	Nebulizers
Product Codes	See Attachment
GMDN Codes	See attachment
EC Representative	Emergo Europe - Prinsessegracht 20, 2514 AP The Hague, The Netherlands
We, the manufacturer hereby declare under sole 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

	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

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

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