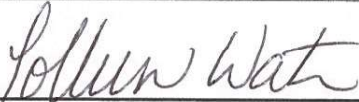


Legal Manufacturer	Vyaire Medical, Inc. - 26125 North Riverwoods Blvd., Mettawa, IL 60045, USA
Product	Oxygen and Aerosol Delivery Devices
Product Codes	See Attachment
GMDN Codes	See attachment
EC Representative	Emergo Europe - Prinsessegracht 20, 2514 AP The Hague, The Netherlands
<p>We, the manufacturer 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.</p>	
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

30 JAN 2020
 Date and Place
 26125 N. Riverwoods Blvd.
 Mettawa, IL 60045 USA


 QA Manufacturing Site Representative
 Indra Montoya

27 Jan 2020
 Date and Place
 Cerrada Vía de la Producción No. 85
 PIMSA III, Mexicali, B.C. México


 OEM Quality Designee
 Nate Badii

27 JAN 2020
 Date and Place
 510 Technology Dr.
 Irvine, CA 92618 USA

Attachment

Product Device Listing

Product Number	Description	EU Class	Rule (s)	GMDN Code	Type of CE Marking	Technical File
001000	AirLife™ Universal Mouthpiece Polyethylene	Ila	5	61346	CE 2797	RT-10
001500	AirLife™ Trach Tee Adapter with 22mm O.D. Arms, 15mm I.D. Base	Ila	2	61346	CE 2797	RT-10
001501	Airlife™ Trach "T" Adapter with Drainage Bag with 22 mm OD Arms, 15 mm ID Base with 500 cc Drainage Bag, Two Oxygen Tube Connectors and Strap Hanger	Ila	2	61346	CE 2797	RT-10
001507	AirLife™ Trach Tee Oxygenator with Trach Tee (6") 15 cm Flextube, Oxygen Stem Connector, and Thermo-Suction Port	Ila	2	61346	CE 2797	RT-10
001550	AirLife™ Ventilator Elbow with Suction Port and Cap 22 mm I.D. x 22 mm O.D. Inlet Arm, 15 mm I.D. Base	Ila	2	61346	CE 2797	RT-10
001560	AirLife™ Trach Mist Unit with Elbow, Trach Elbow with Valves, "Y" with 2 Liter Drainage Bag and Valves Plus Hanger	Ila	2	61346	CE 2797	RT-10
001561	AirLife™ Trach Mist Unit, "Y" with 2 Liter Drainage Bag and Safety Valve Plus Hanger	Ila	2	61346	CE 2797	RT-10
001562	AirLife™ Aerosol Drainage Unit, "Y" with 2 Liter Drainage Bag Plus Hanger	Ila	2	61346	CE 2797	RT-10
001840	Airlife™ Universal Oxygen Nut and Nipple Connection	Ila	2	61346	CE 2797	RT-10
001841	AirLife™ Oxygen Swivel Connector Male/Male	Ila	2	61346	CE 2797	RT-10

Product Number	Description	EU Class	Rule (s)	GMDN Code	Type of CE Marking	Technical File
001842	AirLife™ Oxygen Swivel Connector Male/Female	Ila	2	61346	CE 2797	RT-10
001861	AirLife™ Water Trap for Oxygen Tubing	Ila	2	31286	CE 2797	RT-10
002016	AirLife™ Cannula Ear Covers	Ila	5	35201	CE 2797	RT-10
001309	Airlife™ Nasal Oxygen Cannula Curved, Flared Tip, Over-The-Ear Style	Ila	5	35201	CE 2797	RT-10
001311	Airlife™ Nasal Oxygen Cannula Curved, Nonflared Tip, Over-The-Ear Style	Ila	5	35201	CE 2797	RT-10
001200	Airlife™ Adult Oxygen Mask Vinyl, Under-the-Chin Style, Medium Concentration Mask	Ila	2	35171	CE 2797	RT-10
001201	Airlife™ Adult Oxygen Mask Vinyl, Under-the-Chin Style, Medium Concentration Mask with 7' (2.1m) Tubing	Ila	2	35171	CE 2797	RT-10
001202	Airlife™ Adult Oxygen Mask Vinyl, Under-the-Chin Style, 3 in 1 Mask with Safety Vent	Ila	2	35171	CE 2797	RT-10
001203	Airlife™ Adult Oxygen Mask Vinyl, Under-the-Chin Style, 3 in 1 Mask with Safety Vent and 7' (2.1m) Crush Resistant Oxygen Tubing	Ila	2	35171	CE 2797	RT-10
001204	AirLife™ Adult Oxygen Mask Vinyl, Under-the-Chin Style, High Concentration, Rebreather Mask (No Valves)	Ila	2	35171	CE 2797	RT-10
001205	Airlife™ Adult Oxygen Mask Vinyl, Under-the-Chin Style, High Concentration Rebreather Mask (No Valves) with 7' (2.1m) Crush Resistant Oxygen Tubing	Ila	2	35171	CE 2797	RT-10
001206	AirLife™ Adult Aerosol Mask Vinyl, (Under-The-Chin Style)	Ila	2	35171	CE 2797	RT-10

Product Number	Description	EU Class	Rule (s)	GMDN Code	Type of CE Marking	Technical File
001207	AirLife™ Adult Aerosol Mask Vinyl, Under-The-Chin Style High Concentration	Ila	2	35171	CE 2797	RT-10
001208	Adult Aerosol Mask Vinyl, Under-The-Chin Style with 6' (1.8m) Corrugated Tubing	Ila	2	35171	CE 2797	RT-10
001210	AirLife™ Adult Oxygen Mask Vinyl, Under-the-Chin Style, 3 in 1 Mask without Safety Vent, with 7' (2.1m) Crush Resistant Oxygen Tubing	Ila	2	35171	CE 2797	RT-10
001211	AirLife™ Adult Oxygen Mask Vinyl, Under-the-Chin Style, High Concentration, Nonrebreather Mask with Safety Vent and 7' (2.1m) Supply Tubing	Ila	2	35173	CE 2797	RT-10
001212	AirLife™ Adult Oxygen Mask Vinyl, Under-the-Chin Style, High Concentration, Nonrebreather Mask Without Safety Vent, With 7' (2.1m) Supply Tubing	Ila	2	35173	CE 2797	RT-10
001220	AirLife™ Face Tent Mask Vinyl	Ila	2	35175	CE 2797	RT-10
001221	AirLife™ Face Tent Mask Vinyl, with 6' (1.8m) Corrugated Tubing	Ila	2	35175	CE 2797	RT-10
001255	Airlife™ Adult Dual Dial Venturi Style Mask With 6" (15 cm) Flextube, Color Coded Low and Medium Concentration Dials, High Humidity Adapter / Humidification Hood, 7' (2.1 m) Crush Resistant Oxygen Tubing	Ila	2	35175	CE 2797	RT-10
001259	Airlife™ Pediatric Dual Dial Venturi Style Mask With 6" (15 cm) Flextube, Color Coded Low and Medium Concentration Dials, High	Ila	2	35175	CE 2797	RT-10

Product Number	Description	EU Class	Rule (s)	GMDN Code	Type of CE Marking	Technical File
	Humidity Adapter / Humidification Hood, 7' (2.1 m) Crush Resistant Oxygen Tubing					
001260	AirLife™ Pediatric Oxygen Mask Vinyl, Short Style, Medium Concentration Mask with 7' (2.1m) Tubing	Ila	2	35171	CE 2797	RT-10
001261	AirLife™ Pediatric Aerosol Mask Vinyl, Short Style	Ila	2	35171	CE 2797	RT-10
001262	AirLife™ Pediatric Oxygen Mask Vinyl, Under the Chin Style, Medium Concentration Mask with 7' (2.1m) Tubing	Ila	2	35171	CE 2797	RT-10
001263	AirLife™ Pediatric Aerosol Mask Vinyl, Under the Chin Style	Ila	2	35171	CE 2797	RT-10
001265	AirLife™ Pediatric Oxygen Mask Vinyl, Short Style, High Concentration, Rebreather Mask (No Valves) with 7' (2.1m) Crush Resistant Oxygen Tubing	Ila	2	35171	CE 2797	RT-10
001267	AirLife™ Pediatric Oxygen Mask Vinyl, Under the Chin Style, High Concentration, Rebreather Mask (No Valves) with 7' (2.1m) Crush Resistant Oxygen Tubing	Ila	2	35171	CE 2797	RT-10
001268	AirLife™ Pediatric Oxygen Mask Vinyl, Under the Chin Style, 3 in 1 Mask with Safety Vent and 7' (2.1m) Crush Resistant Oxygen Tubing	Ila	2	35171	CE 2797	RT-10
001269	AirLife™ Pediatric Oxygen Mask Vinyl, Under-the-Chin Style, High Concentration, Nonrebreather Mask with Safety Vent and 7' (2.1m) Supply Tubing	Ila	2	35173	CE 2797	RT-10

Product Number	Description	EU Class	Rule (s)	GMDN Code	Type of CE Marking	Technical File
001361	AirLife™ Adult Oxygen Mask Vinyl, Under-the-Chin Style Medium Concentration Mask with 7' (2.1 m) U/Connect-It Oxygen Tubing	Ila	2	35171	CE 2797	RT-10
001362	AirLife™ Adult Oxygen Mask Vinyl, Under-the-Chin Style, 3 in 1 Mask with 7' (2.1 m) Crush-Resistant Tubing and U/Connect-It Adapter	Ila	2	35171	CE 2797	RT-10
001363	AirLife™ Adult Oxygen Mask Vinyl, Under-the-Chin Style, 6" (15cm) Flextube, Six Diluter Jets, Nebulizer Hood, 7' (2.1 m) Oxygen Tubing and U/Connect-It Adapter	Ila	2	35171	CE 2797	RT-10
001302	Airlife™ Oxygen Tubing 7' (2.1m) Crush Resistant Oxygen Tubing, Vinyl Tipped	Ila	2	12875	CE 2797	RT-10
001303	AirLife™ Oxygen Tubing 14' (4.3m) Crush Resistant Lumen, Vinyl Tipped	Ila	2	12875	CE 2797	RT-10
001303GRN	AirLife™ Oxygen Tubing 14' (4.3m) Green Crush Resistant Lumen, Vinyl Tipped	Ila	2	12875	CE 2797	RT-10
001304	Airlife™ Oxygen Tubing 21' (6.4m) Crush Resistant Oxygen Tubing, Vinyl Tipped	Ila	2	12875	CE 2797	RT-10
001305	Airlife™ Oxygen Tubing 25' (7.6m) Crush Resistant Oxygen Tubing, Vinyl Tipped	Ila	2	12875	CE 2797	RT-10
001305GRN	AirLife™ Oxygen Tubing 25' (7.6m) Green Crush Resistant Lumen, Vinyl Tipped	Ila	2	12875	CE 2797	RT-10
001306	Airlife™ Oxygen Tubing 50' (15.2m) Crush Resistant Oxygen Tubing, Vinyl Tipped	Ila	2	12875	CE 2797	RT-10
001306GRN	AirLife™ Oxygen Tubing 50' (15.2m) Green Crush	Ila	2	12875	CE 2797	RT-10

Product Number	Description	EU Class	Rule (s)	GMDN Code	Type of CE Marking	Technical File
	Resistant Lumen, Vinyl Tipped					
001330	AirLife™ Smooth Bore Oxygen Tubing 7' (2.1m) Vinyl Tipped	Ila	2	12875	CE 2797	RT-10
001350	AirLife™ U/Connect-it Oxygen Tubing 7' (2.1 m) Crush Resistant Oxygen Tubing, Vinyl Tipped	Ila	5	12875	CE 2797	RT-10
001400	AirLife™ Corrugated Flexible EVA Tubing for Aerosol and IPPB Use 6' (1.8m) Length, 22mm I.D.	Ila	2	12875	CE 2797	RT-10
001404	AirLife™ Corrugated Flexible EVA Tubing Segmented 100' (30.5 m) Roll	Ila	2	12875	CE 2797	RT-10
001405	AirLife™ Corrugated Flexible EVA Tubing for Aerosol and IPPB Use Segmented 100' (30.5 m) Length, 22mm I.D. Flat Pack	Ila	2	12875	CE 2797	RT-10
001410	AirLife™ Corrugated Flexible EVA Tubing for Aerosol and IPPB Use Segmented 6' (1.8 m) Length, 22mm I.D.	Ila	2	12875	CE 2797	RT-10
001420	AirLife™ Corrugated Flexible Polyethylene and EVA Tubing for Aerosol and IPPB Use 6' (1.8 m) Length, 22mm I.D.	Ila	2	12875	CE 2797	RT-10
001421	AirLife™ Corrugated Flexible Polyethylene and EVA Tubing 5' (1.5 m) Length, 22 mm I.D.	Ila	2	12875	CE 2797	RT-10
001426	AirLife™ Corrugated Flexible Polyethylene and EVA Tubing Segmented 100 Ft. (30.5m) Roll for Aerosol and IBPB Use	Ila	2	12875	CE 2797	RT-10
001427	AirLife™ Corrugated Flexible Polyethylene and EVA	Ila	2	12875	CE 2797	RT-10

Product Number	Description	EU Class	Rule (s)	GMDN Code	Type of CE Marking	Technical File
	Tubing for Aerosol and IPPB Use Segmented 100' (30.5 m) Length, 22mm I.D. Flat Pack					
001450	AirLife™ Corrugated Flexible Polyethylene and EVA Tubing for Aerosol and IPPB Use Segmented 6' (1.8 m) Length, 22mm I.D.	Ila	2	12875	CE 2797	RT-10
001504	AirLife™ Ventilator Monitoring Adapter Circuit	Ila	2	61346	CE 2797	RT-10
001320	Airlife™ Nasal Oxygen Cannula Curved, Flared Tip, with 7' (2.1 m) Crush Resistant Tubing, Over-The-Ear Style	Ila	5	35201	CE 2797	RT-10
001321	AirLife™ Nasal Oxygen Cannula Curved, Flared Tip, with 14' (4.3 m) Crush Resistant Tubing, Over-The-Ear Style	Ila	5	35201	CE 2797	RT-10
001322	AirLife™ Nasal Oxygen Cannula Curved, Flared Tip, with 21' (6.4m) Crush Resistant Tubing, Over-The-Ear Style	Ila	5	35201	CE 2797	RT-10
001325	Airlife™ Nasal Oxygen Cannula Curved, Nonflared Tip, with 7' (2.1 m) Crush Resistant Tubing, Over-The-Ear Style	Ila	5	35201	CE 2797	RT-10
001326	AirLife™ Nasal Oxygen Cannula Curved, Nonflared Tip, with 14' (4.3m) Crush Resistant Tubing, Over-The-Ear Style	Ila	5	35201	CE 2797	RT-10
001327	AirLife™ Nasal Oxygen Cannula Curved, Nonflared Tip, with 21' (6.4m) Crush Resistant Tubing, Over-The-Ear Style	Ila	5	35201	CE 2797	RT-10

Product Number	Description	EU Class	Rule (s)	GMDN Code	Type of CE Marking	Technical File
001329	AirLife™ Nasal Oxygen Cannula Curved, Nonflared Tip, with 50' (15.2m) Crush Resistant Tubing, Over-The-Ear Style	Ila	5	35201	CE 2797	RT-10
001365	AirLife™ Nasal Oxygen Cannula Curved, Flared Tip, with 7' (2.1m) Crush Resistant Tubing, and U/Connect-It Adapter Over-The-Ear Style	Ila	5	35201	CE 2797	RT-10
001366	AirLife™ Nasal Oxygen Cannula Curved, Nonflared Tip, with 7' (2.1m) Crush Resistant Tubing, and U/Connect-It Adapter Over-The-Ear Style	Ila	5	35201	CE 2797	RT-10
002600	AirLife™ Adult Cushion Nasal Cannula, 7' (2.1m) Crush Resistant Oxygen Tubing	Ila	5	35201	CE 2797	RT-10
002600-14	AirLife™ Adult Cushion Nasal Cannula, 14' (4.3m) Crush Resistant Supply Tube	Ila	5	35201	CE 2797	RT-10
002600-14U	AirLife™ Adult Cushion Nasal Cannula, 4' (1.2m) Crush Resistant Supply Tube	Ila	5	35201	CE 2797	RT-10
002600-25	AirLife™ Adult Cushion Nasal Cannula, 25' (7.6m) Crush Resistant Supply Tube	Ila	5	35201	CE 2797	RT-10
002600-50	AirLife™ Adult Cushion Nasal Cannula, 50' (15.2m) Crush Resistant Supply Tube	Ila	5	35201	CE 2797	RT-10
002601	Airlife™ Infant Cushion Nasal Cannula, 7' (2.1 m) Crush Resistant Oxygen Tubing	Ila	5	35201	CE 2797	RT-10
002602	Airlife™ Pediatric Cushion Nasal Cannula, 7' (2.1 m) Crush Resistant Oxygen Tubing	Ila	5	35201	CE 2797	RT-10

Product Number	Description	EU Class	Rule (s)	GMDN Code	Type of CE Marking	Technical File
002606	AirLife™ Adult Cushion Nasal Cannula without Oxygen Supply Tube	Ila	5	35201	CE 2797	RT-10
002611	AirLife™ Neonate Cushion Nasal Cannula, 7' (2.1 m) Crush resistant Oxygen Tubing	Ila	5	35201	CE 2797	RT-10
002616	AirLife™ Mini Cushion Nasal Cannula, with 7' (2.1m) Crush Resistant Supply Tube For Flows Up to 3 LPM	Ila	5	35201	CE 2797	RT-10
002692	AirLife™ Pediatric Cushion Nasal Cannula, with 7' (2.1m) Crush Resistant Supply Tube and U/Connect-It Adapter	Ila	5	35201	CE 2797	RT-10
002699	AirLife™ Adult Cushion Nasal Cannula, with 7' (2.1m) Crush Resistant Supply Tube and U/Connect-It Adapter	Ila	5	35201	CE 2797	RT-10
002707	AirLife™ Adult Demand Nasal Cannula with 4' (1.2 m) Dual Lumen Supply Tube For Use with Dual-Port Oxygen Conserving Regulator	Ila	5	35201	CE 2797	RT-10
FM2600	AirLife™ Adult Cushion Nasal Cannula, with Foam Ear Covers and 7' (2.1m) Crush Resistant Oxygen Tubing	Ila	5	35201	CE 2797	RT-10
FM2602	AirLife™ Pediatric Cushion Nasal Cannula, with Foam Ear Covers and 7' (2.1m) Crush Resistant Oxygen Tubing	Ila	5	35201	CE 2797	RT-10
FM2606	AirLife™ Adult Cushion Nasal Cannula, with Foam Ear Covers, without Oxygen Tubing	Ila	5	35201	CE 2797	RT-10
FM2614	AirLife™ Adult Cushion Nasal Cannula, with Foam Ear	Ila	5	35201	CE 2797	RT-10

Product Number	Description	EU Class	Rule (s)	GMDN Code	Type of CE Marking	Technical File
	Covers and 14' (4.3m) Crush Resistant Oxygen Tubing					
FM2625	AirLife™ Adult Cushion Nasal Cannula, with Foam Ear Covers and 25' (7.6m) Crush Resistant Oxygen Tubing	Ila	5	35201	CE 2797	RT-10
FM2692	AirLife™ Pediatric Cushion Nasal Cannula, with Foam Ear Covers and 7' (2.1m) Crush Resistant Oxygen Tubing, and with U/Connect-It Adapter	Ila	5	35201	CE 2797	RT-10
FM2699	AirLife™ Adult Cushion Nasal Cannula, with Foam Ear Covers and 7' (2.1m) Crush Resistant Oxygen Tubing, and with U/Connect-It Adapter	Ila	5	35201	CE 2797	RT-10
SFT2600	AirLife™ Adult Cushion Nasal Cannula, 7' (2.1m) Crush Resistant Oxygen Tubing	Ila	5	35201	CE 2797	RT-10
SFT2601	AirLife™ Infant Cushion Nasal Cannula, 7' (2.1m) Crush Resistant Oxygen Tubing	Ila	5	35201	CE 2797	RT-10
SFT2602	AirLife™ Pediatric Cushion Nasal Cannula, 7' (2.1m) Crush Resistant Oxygen Tubing	Ila	5	35201	CE 2797	RT-10
SFT2606	AirLife™ Adult Cushion Nasal Cannula without Oxygen Tubing	Ila	5	35201	CE 2797	RT-10
SFT2611	AirLife™ Neonate Cushion Nasal Cannula, 7' (2.1m) Crush Resistant Oxygen Tubing	Ila	5	35201	CE 2797	RT-10
SFT2614	AirLife™ Adult Cushion Nasal Cannula, 14' (4.3m) Crush Resistant Oxygen Tubing	Ila	5	35201	CE 2797	RT-10
SFT2614U	AirLife™ Adult Cushion Nasal Cannula, 14' (4.3m) Crush	Ila	5	35201	CE 2797	RT-10

Product Number	Description	EU Class	Rule (s)	GMDN Code	Type of CE Marking	Technical File
	Resistant Oxygen Tubing, and U/Connect-It Adapter					
SFT2625	AirLife™ Adult Cushion Nasal Cannula, 25' (7.6m) Crush Resistant Oxygen Tubing	Ila	5	35201	CE 2797	RT-10
SFT2692	AirLife™ Pediatric Cushion Nasal Cannula, 7' (2.1m) Crush Resistant Oxygen Tubing, and U/Connect-It Adapter	Ila	5	35201	CE 2797	RT-10
SFT2699	AirLife™ Adult Cushion Nasal Cannula, 7' (2.1m) Crush Resistant Oxygen Tubing, and U/Connect-It Adapter	Ila	5	35201	CE 2797	RT-10
2802F -10	AirLife™ Nasal ETCO2 Cannula, Pediatric with 7' O2 tube and 7' CO2 tube with female luer connector and 22mm (I.D.) x 6mm (O.D.) adapter	Ila	5	35201	CE 2797	RT-10
2802M-10	AirLife™ Nasal ETCO2 Cannula, Pediatric with 7' O2 tube and 7' CO2 tube with male luer connector and 22mm (I.D.) x 6mm (O.D.) adapter	Ila	5	35201	CE 2797	RT-10
2811F-10	AirLife™ Nasal ETCO2 Cannula, Adult with 7' O2 tube and 2" CO2 tube with female luer connector and 22mm (I.D.) x 6mm (O.D.) adapter	Ila	5	35201	CE 2797	RT-10
2811M-10	AirLife™ Nasal ETCO2 Cannula, Adult with 7' O2 tube and 2" CO2 tube with male luer connector and 22mm (I.D.) x 6mm (O.D.) adapter	Ila	5	35201	CE 2797	RT-10
2812F-10	AirLife™ Nasal ETCO2 Cannula, Adult with 7' O2 tube and 7' CO2 tube with female luer connector and	Ila	5	35201	CE 2797	RT-10

Product Number	Description	EU Class	Rule (s)	GMDN Code	Type of CE Marking	Technical File
	22mm (I.D.) x 6mm (O.D.) adapter					
2812M-10	AirLife™ Nasal ETCO2 Cannula, Adult with 7' O2 tube and 7' CO2 tube with male luer connector and 22mm (I.D.) x 6mm (O.D.) adapter	Ila	5	35201	CE 2797	RT-10
28M2F	AirLife™ ETCO2 Sample Line, 10' tube with 1 male and 1 female luer connector	Ila	2	35201	CE 2797	RT-10
28M2M	AirLife™ ETCO2 Sample Line, 10' tube with 2 male luer connectors	Ila	2	35201	CE 2797	RT-10
001225	AirLife™ Adult Tracheostomy Mask	Ila	2	35179	CE 2797	RT-10
001226	AirLife™ Pediatric Tracheostomy Mask	Ila	2	35179	CE 2797	RT-10
001227	Airlife™ Adult Tracheostomy Mask (Large)	Ila	2	35179	CE 2797	RT-10
001240	Airlife™ Adult Venturi Style Mask Vinyl, Under-the-Chin Style	Ila	2	35175	CE 2797	RT-10
001244	Airlife™ Adult Venturi Style Mask Vinyl, Under-the-Chin Style, 35%	Ila	2	35175	CE 2797	RT-10
001245	Airlife™ Adult Venturi Style Mask Vinyl, Under-the-Chin Style, 40%	Ila	2	35175	CE 2797	RT-10
001247	Airlife™ Venturi Style Trach Tee	Ila	2	35175	CE 2797	RT-10
001248	Airlife™ Adult Venturi Style Tracheostomy Mask	Ila	2	35175	CE 2797	RT-10
001250	Airlife™ Pediatric Venturi Style Mask Vinyl, Under-the-Chin Style	Ila	2	35175	CE 2797	RT-10
AM-1000	AirLife™ Open Oxygen Mask, Medium	Ila	2	58810	CE 2797	RT-10
AM-1100	AirLife™ Open Oxygen Mask, Large	Ila	2	58810	CE 2797	RT-10

Product Number	Description	EU Class	Rule (s)	GMDN Code	Type of CE Marking	Technical File
AM-1200	AirLife™ Open Oxygen Mask, Small	Ila	2	58810	CE 2797	RT-10

GMDN Code	GMDN Term
12875	Oxygen administration tubing
61346	Tube/mask breathing circuit connector, non-sterile, single-use
35171	Rebreathing Oxygen Face Mask
35175	Venturi Oxygen Face Mask
35201	Basic nasal oxygen cannula
35173	Non-rebreathing oxygen face mask
35179	Tracheostomy mask, aerosol
31286	Breathing circuit condensate trap, reusable
58810	Vortex oxygen face mask