

## Manufacturer's Declaration to Regulation (EU) 2023/607

According to Regulation (EU)2017/745 (MDR) and regarding the transitional provisions, Vyairé Medical, Inc. declares the amendments to Article 120 of the MDR, as amended by Regulation (EU) 2023/607 applies to the following device(s):

Manufacturer name:	Vyairé Medical, Inc.
Manufacturer address and contact details:	26125 N Riverwoods Blvd, Mettawa, IL 60045 USA
Single Registration Number (SRN) (if available):	US-MF-000008254

Authorised Representative name	Emergo Europe BV
Authorised Representative address and contact details	Westervoortsedijk 60 6827 AT, Arnhem THE NETHERLANDS
Single Registration Number (SRN)	NL-AR-000000116

Notified body name (if applicable)	BSI Group The Netherlands B.V. <input type="checkbox"/> See attached schedule
Notified body number (if applicable)	2797 <input type="checkbox"/> See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	CE 703694 <input type="checkbox"/> See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	26 May 2024 <input type="checkbox"/> See attached schedule
End date of extended validity/transition period	31 December 2028 <input type="checkbox"/> See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*<sup>1</sup>
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➤ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021, was/were not withdrawn by 20 March 2023
- *Choose applicable statements:*
  - Expired *before* 20 March 2023:
    - Before the original date of expiry as indicated on the Directive Certificate, we and the notified body have signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment in respect of the device covered by the expired certificate or in respect of a device intended to substitute that device
    - A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request)
    - A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)
  - Expired/*expires after* 20 March 2023:
    - A formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s)

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<sup>1</sup> The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

listed in the attached schedule or its substitute and a signed written agreement is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

➤ **Up-classified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

*Choose one applicable statement:*

- A formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its substitute and a signed written agreement is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

➤ **Quality Management System (QMS)**

• *Choose one applicable statement:*

- A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.
- A QMS in accordance with Article 10(9) MDR is in place.
- A notified body has issued the attached certificate for the MDR-compliant QMS.

➤ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- The device(s) has/have not been significantly changed in its/their design and intended purpose since 26 May 2021.
- The device(s) do not present an unacceptable risk to health or safety of patients, users, or other persons, or to other aspects of the protection of public health.

**Signed for and on behalf of the manufacturer:**

Vyairé Medical, Inc.

Mettawa, IL on the 16th of May 2024



*Electronically signed by: Erin Salbilla  
Reason: I approve this document  
Date: May 16, 2024 20:28 CDT*

Erin Salbilla, Senior Director, Quality Systems



## Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Device identification	Directive Certificate number(s) to which this confirmation is made	Original expiry date <sup>2</sup>	Notified Body name and number	Classification and rule under the MDR	End date of extended validity / transition period	Substitute Device <input checked="" type="checkbox"/> <i>Not applicable</i>
<i>Active Humidification System:</i>  AirLife™ Autofill Humidification Chamber	CE 703694	26 May 2024	BSI 2797	Class IIa	31 December 2028	Not Applicable
<i>Active Humidification System:</i>  AirLife™ Respiratory Heated Breathing Circuits <ul style="list-style-type: none"> <li>• AirLife™ Infant Heated Wire Circuit dual-limb, dual -heat, high-flow circuit</li> <li>• AirLife™ Infant Heated Wire Circuit single - limb, single heat, continuous -flow circuit</li> </ul>	CE 703694	26 May 2024	BSI 2797	Class IIa	31 December 2028	Not Applicable

<sup>2</sup> As indicated on the Directive Certificate prior to the extension of the validity.



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<ul style="list-style-type: none"> <li>• AirLife™ Adult Heated Wire Circuit single- limb, single- heated circuit</li> <li>• AirLife™ Adult Heated Wire Circuit dual-limb, dual-heated circuit</li> <li>• AirLife™ Infant Single Limb Heated Wire Circuit Kit Single- limb, Single-heated, continuous-flow circuit (&gt;4 Umin) - Contains AH032 Circuit, AH290 Chamber</li> <li>• AirLife™ Infant Heated Wire Circuit Kit Dual- limb, Dual-heat, high- flow circuit (&gt;4 Umin) - Contains AH165 Circuit, AH290 Chamber</li> <li>• AirLife™ Adult Heated Wire Circuit Kit - Single-limb, Single-heated circuit Contains AH102 circuit, AH290 Chamber</li> <li>• AirLife™ Adult Heated Wire Circuit Kit-Dual-limb, Dual-heated circuit- Contains AH180 Circuit, AH290 Chamber</li> <li>• AirLife™ Autofill Humidification Chamber</li> </ul>						



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<p><i>Anesthesia Circuits &amp; Accessory Devices</i></p> <p>Anesthesia Breathing Circuit, Single – Use</p> <ul style="list-style-type: none"> <li>• One Lung – Anesthesia Circuit</li> <li>• Limb-O Single Limb Anesthesia Breathing Circuit</li> <li>• Vital Signs® Breathing Bag</li> <li>• Vital Signs® Adult Anesthesia Breathing Circuit</li> <li>• Vital Signs® Anesthesia Ventilator Circuit</li> <li>• Vital Signs® Pediatric Anesthesia Breathing Circuit</li> <li>• Vital Signs® Adult Breathing Circuit 60 inch (1.5 m) hose</li> <li>• Vital Signs® Jackson-Rees Circuits</li> <li>• Extension Set For Vital Signs® Adult Anesthesia Breathing Circuit</li> <li>• Vital Signs® Resp Accessories</li> <li>• Vital Signs™ Hose Adapter</li> <li>• Vital Signs™ Luer Capped T</li> <li>• Vital Signs™ Elbow-Luer Port</li> </ul>	CE 703694	26 May 2024	BSI 2797	Class IIa	31 December 2028	Not Applicable



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<ul style="list-style-type: none"> <li>24 Inch Exp Extension Set</li> </ul>						
<p><i>Anesthesia Circuits &amp; Accessory Devices</i></p> <p>Anesthesia Face Mask, Single – Use</p> <ul style="list-style-type: none"> <li>Vital Signs® Neonate Face Mask Size 1</li> <li>Vital Signs® Infant Face Mask Size 2</li> <li>Vital Signs® Toddler Face mask with Adjustable Air Cushion Size 3</li> <li>Vital Signs® Child/Small Adult Face Mask with Adjustable Air Cushion Size 4</li> <li>Vital Signs® Adult Face Mask with Adjustable Air Cushion Size 5</li> <li>Vital Signs® Extra Large Face Mask with Adjustable Air Cushion Size 6</li> <li>Vital Signs™ Lite Anesthesia Face Mask Neonate - Size 1</li> <li>Vital Signs™ Lite Anesthesia Face Mask Infant - Size 2</li> <li>Vital Signs™ Toddler Face Mask</li> <li>Vital Signs™ Child Face Mask</li> </ul>	CE 703694	26 May 2024	BSI 2797	Class IIa	31 December 2028	Not Applicable



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<ul style="list-style-type: none"> <li>• Vital Signs® Premie Face Mask Size 0</li> <li>• Vital Signs® Child/Small Adult Face Mask with Adjustable Air Cushion</li> <li>• Vital Signs™ Lite Anesthesia Face Mask Small Adult - Size 5</li> <li>• Vital Signs™ Lite Anesthesia Face Mask Medium Adult - Size 6</li> <li>• Vital Signs™ Lite Anesthesia Face Mask Large Adult - Size 7</li> <li>• Vital Signs™ Lite Anesthesia Face Mask Toddler – Size 3</li> <li>• Vital Signs™ Lite Anesthesia Face Mask Toddler – Size 4</li> </ul>						
<p><i>Anesthesia Circuits &amp; Accessory Devices:</i></p> <p>Gas- Sampling/ Monitoring Respiratory Tubing, Single-Use, Non-Sterile</p> <ul style="list-style-type: none"> <li>• Vital Signs™ Gas Sampling Interface</li> </ul>	CE 703694	26 May 2024	BSI 2797	Class IIa	31 December 2028	Not Applicable
<p><i>ENFLOW Blood Warmer &amp; Accessories</i></p> <ul style="list-style-type: none"> <li>• enFlow IV Fluid/Blood Warmer</li> <li>• enFlow Controller Unit</li> </ul>	CE 703694	26 May 2024	BSI 2797	Class IIb	31 December 2028	Not Applicable





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EnFlow Disposable Cartridge <ul style="list-style-type: none"> <li>• enFlow Disposable Cartridge</li> <li>• enFlow Disposable Cartridge with IV Extension Set</li> </ul>	CE 703694	26 May 2024	BSI 2797	Class IIa	31 December 2028	Not Applicable
Catheters for Respiratory Therapy and Adaptors (Sterile & Non-Sterile) <ul style="list-style-type: none"> <li>• AirLife Tri-Flo Suction Catheter with Control 14Fr</li> <li>• AirLife Tri-Flo Suction Catheter with Multifit Rigid Connector, 14Fr</li> <li>• AirLife Tri-Flo Suction Catheter, 10Fr</li> <li>• AirLife Tri-Flo Suction Catheter with Multifit Rigis Connector, 10Fr</li> <li>• AirLife Tri-Flo Suction Catheter with Control 18Fr</li> <li>• AirLife Verso Airway Access Adapter</li> <li>• AirLife Verso T Airway Access Adapter</li> <li>• AirLife Verso 90 Airway Access Adapter</li> </ul>	CE 703694	26 May 2024	BSI 2797	Class IIa	31 December 2028	Not Applicable



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<ul style="list-style-type: none"> <li>• AirLife Neo-Verso Airway Access Adapter with Swivel</li> <li>• AirLife Neo-Verso 'Y' Airway Access Adapter for Endotracheal Tubes</li> <li>• AirLife Closed Suction Catheter 10 Fr</li> <li>• AirLife Closed Suction Catheter 12 Fr</li> <li>• AirLife Closed Suction Catheter 14 Fr</li> <li>• AirLife Closed Suction Catheter 16 Fr</li> <li>• AirLife Closed Suction Catheter - Directional Tip 14 Fr</li> <li>• AirLife Closed Suction Catheter - Tracheostomy Length 10 Fr</li> <li>• AirLife Closed Suction Catheter - Tracheostomy Length 12 Fr</li> <li>• AirLife Closed Suction Catheter - Tracheostomy Length 14 Fr</li> <li>• AirLife Closed Suction Catheter - Tracheostomy Length 16 Fr</li> <li>• AirLife Closed Suction Catheter - Neonatal 5 Fr</li> </ul>						



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<ul style="list-style-type: none"> <li>• AirLife Closed Suction Catheter - Neonatal 6 Fr</li> <li>• AirLife Closed Suction Catheter - Neonatal 7 Fr</li> <li>• AirLife Closed Suction Catheter - Neonatal 8 Fr</li> <li>• AirLife Fluid/Access Catheter - 5 Fr</li> <li>• AirLife Adult Double Swivel Elbow Adapter (41 mL) with 15 mm X 22 mm Flex Tube</li> <li>• AirLife Adult Swivel Tee Piece Adapter (56 mL) with 15 mm X 22 mm Flex Tube</li> <li>• AirLife Adult Swivel Tee Piece Adapter (67 mL) with Omni-Flex Connector and 22 mm X 22 mm Flex Tube</li> <li>• AirLife Closed Suction Adult Catheter Only, Endotracheal, 14 Fr</li> <li>• AirLife Closed Suction Adult Catheter Only, Tracheostomy, 14 Fr</li> <li>• AirLife Closed Suction Kit for Adults, Endotracheal, 14 Fr</li> </ul>						



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<ul style="list-style-type: none"> <li>• AirLife Closed Suction Kit for Adults, Endotracheal, 14 Fr</li> <li>• AirLife Closed Suction Kit for Adults, Tracheostomy, 14 Fr</li> <li>• AirLife Closed Suction Kit for Adults, Tracheostomy, 14 Fr</li> <li>• AirLife Closed Suction Kit for Adults, Tracheostomy, 14 Fr</li> </ul>						
<p><i>Respiratory Non-Heated Circuits and Accessories:</i></p> <p>Non Invasive Ventilation (NIV) Masks</p> <ul style="list-style-type: none"> <li>• AirLife™ Non Invasive Ventilation (NIV) Vented Full Face Mask with Anti-Asphyxiation Valve (Large)</li> <li>• AirLife™ Non Invasive Ventilation (NIV) Vented Full Face Mask with Anti-Asphyxiation Valve (Medium)</li> <li>• AirLife™ Non Invasive Ventilation (NIV) Vented Full Face Mask with Anti-Asphyxiation Valve (Small)</li> <li>• AirLife™ Non Invasive Ventilation (NIV) Non- Vented Full Face Mask</li> </ul>	CE 703694	26 May 2024	BSI 2797	Class IIa	31 December 2028	Not Applicable



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without Anti- Asphyxiation Valve (Large) <ul style="list-style-type: none"> <li>• AirLife™ Non Invasive Ventilation (NIV) Non- Vented Full Face Mask without Anti- Asphyxiation Valve (Medium)</li> <li>• AirLife™ Non Invasive Ventilation (NIV) Non- Vented Full Face Mask without Anti- Asphyxiation Valve (Small)</li> <li>• AirLife™ Non Invasive Ventilation (NIV) Vented Nasal Mask with Anti- Asphyxiation Valve (Large)</li> <li>• AirLife™ Non Invasive Ventilation (NIV) Vented Nasal Mask with Anti- Asphyxiation Valve (Medium)</li> <li>• AirLife™ Non Invasive Ventilation (NIV) Vented Nasal Mask with Anti- Asphyxiation Valve (Small)</li> <li>• AirLife™ Non Invasive Ventilation (NIV) Non- Vented Full Face Mask with Anti-Asphyxiation Valve (Large)</li> </ul>						



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<ul style="list-style-type: none"> <li>AirLife™ Non Invasive Ventilation (NIV) Non- Vented Full Face Mask with Anti-Asphyxiation Valve (Medium)</li> <li>AirLife™ Non Invasive Ventilation (NIV) Non- Vented Full Face Mask with Anti-Asphyxiation Valve (Small)</li> <li>AirLife™ Non Invasive Ventilation (NIV) Non- Vented Nasal Mask with Anti- Asphyxiation Valve (Large)</li> <li>AirLife™ Non Invasive Ventilation (NIV) Non- Vented Nasal Mask with Anti- Asphyxiation Valve (Medium)</li> <li>AirLife™ Non Invasive Ventilation (NIV) Non- Vented Nasal Mask with Anti- Asphyxiation Valve (Small)</li> </ul>						
<p><i>Respiratory Non-Heated Circuits and Accessories:</i></p> <p>SuperNova Nasal PAP Ventilation Device</p> <ul style="list-style-type: none"> <li>SuperNO2VA™ Nasal PAP Ventilation Device, Medium</li> </ul>	CE 703694	26 May 2024	BSI 2797	Class IIa	31 December 2028	Not Applicable



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<ul style="list-style-type: none"> <li>SuperNO2VA™ Nasal PAP Ventilation Device, Large</li> </ul>						
<p><i>Resuscitation Devices:</i></p> <p>Supernova™ Nasal PAP Ventilation</p> <ul style="list-style-type: none"> <li>SuperNO2VA™ Nasal PAP Ventilation System, Medium</li> <li>SuperNO2VA™ Nasal PAP Ventilation System, Large</li> </ul>	CE 703694	26 May 2024	BSI 2797	Class IIa	31 December 2028	Not Applicable
<p><i>Oxygen and Aerosol Delivery Devices:</i></p> <ul style="list-style-type: none"> <li>AirLife™ Adult Oxygen Mask Vinyl, Under-the- Chin Style, Medium Concentration Mask</li> <li>AirLife™ Adult Oxygen Mask Vinyl, Under-the- Chin Style, Medium Concentration Mask with 7' (2.1m) Tubing</li> <li>AirLife™ Adult Oxygen Mask Vinyl, Under-the- Chin Style, 3 in 1 Mask with Safety Vent</li> <li>AirLife™ Adult Oxygen Mask Vinyl, Under-the- Chin Style, 3 in 1 Mask</li> </ul>	CE 703694	26 May 2024	BSI 2797	Class IIa	31 December 2028	Not Applicable



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<p>with Safety Vent and 7' (2.1m) Crush Resistant Oxygen Tubing</p> <ul style="list-style-type: none"> <li>• AirLife™ Adult Oxygen Mask Vinyl, Under-the- Chin Style, High Concentration, Rebreather Mask (No Valves)</li> <li>• AirLife™ Adult Oxygen Mask Vinyl, Under-the- Chin Style, High Concentration Rebreather Mask (No Valves) with 7' (2.1m) Crush Resistant Oxygen Tubing</li> <li>• AirLife™ Adult Aerosol Mask Vinyl, (Under- The-Chin Style)</li> <li>• AirLife™ Adult Aerosol Mask Vinyl, Under-The- Chin Style High Concentration</li> <li>• Adult Aerosol Mask Vinyl, Under-The-Chin Style with 6' (1.8m) Corrugated Tubing</li> <li>• AirLife™ Adult Aerosol Mask Vinyl, Under-The- Chin Style with 5' (1.5m) Corrugated Tubing</li> <li>• AirLife™ Adult Oxygen Mask Vinyl, Under-the- Chin Style, 3 in 1 Mask</li> </ul>						





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without Safety Vent, with 7' (2.1m) Crush Resistant Oxygen Tubing <ul style="list-style-type: none"> <li>• AirLife™ Adult Oxygen Mask Vinyl, Under-the- Chin Style, High Concentration, Nonrebreather Mask with Safety Vent and 7' (2.1m) Supply Tubing</li> <li>• AirLife™ Adult Oxygen Mask Vinyl, Under-the- Chin Style, High Concentration, Nonrebreather Mask without Safety Vent, with 7' (2.1m) Supply Tubing</li> <li>• AirLife™ Face Tent Mask Vinyl</li> <li>• AirLife™ Face Tent Mask Vinyl, with 6' (1.8m) Corrugated Tubing</li> <li>• AirLife™ Face Tent Mask Vinyl, with 5' (1.5m) Corrugated Tubing</li> <li>• AirLife™ Adult Tracheostomy Mask</li> <li>• AirLife™ Pediatric Tracheostomy Mask</li> <li>• AirLife™ Adult Tracheostomy Mask (Large)</li> <li>• AirLife™ Adult Venturi Style Mask Vinyl, Under-the-Chin Style</li> </ul>						



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<ul style="list-style-type: none"> <li>• AirLife™ Adult Venturi Style Mask Vinyl, Under-the-Chin Style, 24%</li> <li>• AirLife™ Adult Venturi Style Mask Vinyl, Under-the-Chin Style, 28%</li> <li>• AirLife™ Adult Venturi Style Mask Vinyl, Under-the-Chin Style, 35%</li> <li>• AirLife™ Adult Venturi Style Mask Vinyl, Under-the-Chin Style, 40%</li> <li>• AirLife™ Venturi Style Trach Tee</li> <li>• AirLife™ Adult Venturi Style Tracheostomy Mask</li> <li>• AirLife™ Pediatric Venturi Style Mask Vinyle, Under-the-Chin Style</li> <li>• 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' (2.1m) Crush Resistant Oxygen Tubing</li> <li>• AirLife™ Pediatric Dual Dial Venturi Style Mask with 6" (15cm) Flextube, Color Coded Low and Medium Concentration Dials, High Humidity</li> </ul>						



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Adapter/ Humidification Hood, 7' (2.1m) Crush Resistant Oxygen Tubing <ul style="list-style-type: none"> <li>• AirLife™ Pediatric Oxygen Mask Vinyl, Short Style, Medium Concentration Mask with 7' (2.1m) Tubing</li> <li>• AirLife™ Pediatric Aerosol Mask Vinyl, Short Style</li> <li>• AirLife™ Pediatric Oxygen Mask Vinyl, Under the Chin Style, Medium Concentration Mask with 7' (2.1m) Tubing</li> <li>• AirLife™ Pediatric Aerosol Mask Vinyl, Under the Chin Style</li> <li>• AirLife™ Pediatric Oxygen Mask Vinyl, Short Style, High Concentration, Rebreather Mask (No Valves)</li> <li>• AirLife™ Pediatric Oxygen Mask Vinyl, Short Style, High Concentration, Rebreather Mask (No Valves)</li> </ul>						



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<ul style="list-style-type: none"> <li>• AirLife™ Pediatric Oxygen Mask Vinyl, Under the Chin Style, High Concentration, Rebreather Mask (No Valves) with 7' (2.1m) Crush Resistant Oxygen Tubing</li> <li>• AirLife™ Pediatric Oxygen Mask Vinyl, Under the Chin Style, 3 in 1 Mask with Safety Vent and 7' (2.1m) Crush Resistant Oxygen Tubing</li> <li>• AirLife™ Pediatric Oxygen Mask Vinyl, Under-the-Chin Style, High Concentration, Nonrebreather Mask with Safety Vent and 7' (2.1m) Supply Tubing</li> <li>• AirLife™ Adult Oxygen Mask Vinyl, Under-the- Chin Style Medium Concentration Mask with 7' (2.1 m) U/Connect-It Oxygen Tubing</li> <li>• 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</li> </ul>						



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<ul style="list-style-type: none"> <li>• 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</li> <li>• AirLife™ Oxygen Tubing 7' (2.1m) Crush Resistant Oxygen Tubing, Vinyl Tipped</li> <li>• AirLife™ Oxygen Tubing 14' (4.3m) Crush Resistant Lumen, Vinyl Tipped</li> <li>• AirLife™ Oxygen Tubing 14' (4.3m) Green Crush Resistant Lumen, Vinyl Tipped</li> <li>• AirLife™ Oxygen Tubing 21' (6.4m) Crush Resistant Oxygen Tubing, Vinyl Tipped</li> <li>• AirLife™ Oxygen Tubing 21' (6.4m) Green Crush Resistant Lumen, Vinyl Tipped</li> <li>• AirLife™ Oxygen Tubing 25' (7.6m) Crush Resistant Oxygen Tubing, Vinyl Tipped</li> </ul>						



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<ul style="list-style-type: none"> <li>• AirLife™ Oxygen Tubing 25' (7.6m) Green Crush Resistant Lumen, Vinyl Tipped</li> <li>• AirLife™ Oxygen Tubing 50' (15.2m) Crush Resistant Oxygen Tubing, Vinyl Tipped</li> <li>• AirLife™ Oxygen Tubing 50' (15.2m) Green Crush Resistant Lumen, Vinyl Tipped</li> <li>• AirLife™ Oxygen Tubing 30' (9.1m) Crush Resistant Lumen, Vinyl Tipped</li> <li>• AirLife™ Oxygen Tubing 40' (12.2m) Crush Resistant 4079-2 Page 41 of 57 Lumen, Vinyl Tipped</li> <li>• AirLife™ Oxygen Tubing 40' (12.2m) Green Crush Resistant Lumen, Vinyl Tipped</li> <li>• AirLife™ Smooth Bore Oxygen Tubing 7' (2.1m) Vinyl Tipped</li> <li>• AirLife™ U/Connect-It Oxygen Tubing 7' (2.1) Crush Resistant Oxygen Tubing, Vinyl Tipped</li> </ul>						



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<ul style="list-style-type: none"> <li>• AirLife™ Corrugated Flexible EVA Tubing for Aerosol and IPPB Use 6’ (1.8m) Length, 22mm I.D.</li> <li>• AirLife™ Corrugated Flexible EVA Tubing Segmented 100’ (30.5 Roll</li> <li>• AirLife™ Corrugated Flexible EVA Tubing for Aerosol and IPPB Use Segmented 100’ (30.5 Length, 22mm I.D. Flat Pack</li> <li>• AirLife™ Corrugated Flexible EVA Tubing for Aerosol and IPPB Use Segmented 6’ (1.8 m) Length, 22mm I.D.</li> <li>• AirLife™ Corrugated Flexible Polyethylene and EVA Tubing for Aerosol and IPPB Use 6’ (1.8 m) Length, 22mm I.D.</li> <li>• AirLife™ Corrugated Flexible Polyethylene and EVA Tubing 5’ (1.5 Length, 22 mm I.D.</li> <li>• AirLife™ Corrugated Flexible Polyethylene and EVA Tubing Segmented 100 Ft. (30.5m) Roll for Aerosol and IBPB Use</li> </ul>						



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<ul style="list-style-type: none"> <li>• AirLife™ Corrugated Flexible Polyethylene and EVA Tubing for Aerosol and IPPB Use Segmented 100' (30.5 m) Length, 22mm I.D. Flat Pack</li> <li>• AirLife™ Corrugated Flexible Polyethylene and EVA Tubing for Aerosol and IPPB Use Segmented 6' (1.8 m) Length, 22mm I.D.</li> <li>• AirLife™ Nasal Oxygen Cannula Curved, Flared Tip, Over-The-Ear Style</li> <li>• AirLife™ Nasal Oxygen Cannula Curved, Nonflared Tip, Over-The-Ear Style</li> <li>• AirLife™ Nasal Oxygen Cannula Curved, Flared Tip, with 7' (2.1m) Crush Resistant Tubing, Over-The-Ear Style</li> <li>• AirLife™ Nasal Oxygen Cannula Curved, Flared Tip, with 14' (4.3 m) Crush Resistant Tubing, Over-The-Ear Style</li> </ul>						





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<ul style="list-style-type: none"> <li>• AirLife™ Nasal Oxygen Cannula Curved, Flared Tip, with 21' (6.4m) Crush Resistant Tubing, Over-The-Ear Style</li> <li>• AirLife™ Nasal Oxygen Cannula Curved, Nonflared Tip, with 7' (2.1m) Crush Resistant Tubing, Over-The-Ear Style</li> <li>• AirLife™ Nasal Oxygen Cannula Curved, Nonflared Tip, 4079-2 Page 42 of 57 with 14' (4.3m) Crush Resistant Tubing, Over-The-Ear Style</li> <li>• AirLife™ Nasal Oxygen Cannula Curved, Nonflared Tip, with 21' (6.4m) Crush Resistant Tubing, Over-The-Ear Style</li> <li>• AirLife™ Nasal Oxygen Cannula Curved, Nonflared Tip, with 21' (6.4m) Crush Resistant Tubing, Over-The-Ear Style</li> <li>• AirLife™ Nasal Oxygen Cannula Curved, Nonflared Tip, with 50' (15.2m) Crush Resistant Tubing, Over-The-Ear Style</li> <li>• AirLife™ Nasal Oxygen Cannula Curved, Flared Tip, with 7' (2.1m) Crush Resistant Tubing, and</li> </ul>						



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<p>U/Connect-It Adapter Over-The-Ear Style</p> <ul style="list-style-type: none"> <li>• AirLife™ Nasal Oxygen Cannula Curved, Nonflared Tip, with 7' (2.1m) Crush Resistant Tubing, and U/Connect- It Adapter Over-The-Ear Style</li> <li>• AirLife™ Cannula Ear Covers</li> <li>• AirLife™ Adult Cushion Nasal Cannula, 7' (2.1m) Crush Resistant Oxygen Tubing</li> <li>• AirLife™ Adult Cushion Nasal Cannula, 4' (1.2m) Crush Resistant Supply Tube</li> <li>• AirLife™ Adult Cushion Nasal Cannula, 14' (4.3m) Crush Resistant Supply Tube</li> <li>• AirLife™ Adult Cushion Nasal Cannula, 4' (1.2m) Crush Resistant Supply Tube</li> <li>• AirLife™ Adult Cushion Nasal Cannula, 25' (7.6m) Crush Resistant Supply Tube</li> </ul>						



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<ul style="list-style-type: none"> <li>• AirLife™ Adult Cushion Nasal Cannula, 50' (15.2m) Crush Resistant Supply Tube</li> <li>• AirLife™ Infant Cushion Nasal Cannula, 7' (2.1m) Crush Resistant Oxygen Tubing</li> <li>• AirLife™ Pediatric Cushion Nasal Cannula, 7' (2.1m) Crush Resistant Oxygen Tubing</li> <li>• AirLife™ Adult Cushion Nasal Cannula without Oxygen Supply Tube</li> <li>• AirLife™ Neonate Cushion Nasal Cannula, 7' (2.1m) Crush Resistant Oxygen Tubing</li> <li>• AirLife™ Mini Cushion Nasal Cannula, with 7' (2.1m) Crush Resistant Supply Tube For Flows Up to 3 LPM</li> <li>• AirLife™ Mini Cushion Nasal Cannula, with 4' (1.2m) Crush Resistant Supply Tube For Flows Up to 3 LPM</li> </ul>						



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<ul style="list-style-type: none"> <li>• AirLife™ Adult Cushion Nasal Cannula, Flared Tip with 4' (1.2m) Crush Resistant Supply Tube</li> <li>• AirLife™ Pediatric Cushion Nasal Cannula without Oxygen Supply Tube</li> <li>• AirLife™ Pediatric Cushion Nasal Cannula, with 7' (2.1m) Crush Resistant Supply Tube and U/Connect-It Adapter</li> <li>• AirLife™ Adult Cushion Nasal Cannula, with 7' (2.1m) Crush Resistant Supply Tube and U/Connect-It Adapter</li> <li>• AirLife™ Adult Demand Nasal Cannula with 4' (1.2 m) Dual Lumen Supply Tube For Use with Dual-Port Oxygen Conserving Regulator</li> <li>• AirLife™ Adult Demand Nasal Cannula with 4' (1.2 m) Dual Lumen Supply Tube For Use with Dual-Port Oxygen Conserving Regulator</li> <li>• AirLife™ Nasal Oxygen Cannula Curved, Nonflared Tip, with 14'</li> </ul>						



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Crush Resistant Oxygen Supply Tubing, with U/Connect-It Adapter <ul style="list-style-type: none"> <li>• AirLife™ Adult Cushion Nasal Cannula, with Foam Ear Covers and 7' (2.1m) Crush Resistant Oxygen Tubing</li> <li>• AirLife™ Pediatric Cushion Nasal Cannula, with Foam Ear Covers and 7' (2.1m) Crush Resistant Oxygen Tubing</li> <li>• AirLife™ Adult Cushion Nasal Cannula, with Foam Ear Covers and 4' (1.2m) Crush Resistant Oxygen Tubing</li> <li>• AirLife™ Adult Cushion Nasal Cannula, with Foam Ear Covers, without Oxygen Tubing</li> <li>• AirLife™ Adult Cushion Nasal Cannula, with Foam Ear Covers and 14' (4.3m) Crush Resistant Oxygen Tubing</li> <li>• AirLife™ Adult Cushion Nasal Cannula, with Foam Ear Covers and</li> </ul>						



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<p>25' (7.6m) Crush Resistant Oxygen Tubing</p> <ul style="list-style-type: none"> <li>• AirLife™ Pediatric Cushion Nasal Cannula, with Foam Ear Covers and 7' (2.1m) Crush Resistant Oxygen Tubing, and with U/Connect-It Adapter</li> <li>• AirLife™ Adult Cushion Nasal Cannula, with Foam Ear Covers and 7' (2.1m) Crush Resistant Oxygen Tubing, and with U/Connect-It Adapter</li> <li>• AirLife™ Adult Cushion Nasal Cannula, 7' (2.1m) Crush Resistant Oxygen Tubing</li> <li>• AirLife™ Infant Cushion Nasal Cannula, 7' (2.1m) Crush Resistant Oxygen Tubing</li> <li>• AirLife™ Pediatric Cushion Nasal Cannula, 7' (2.1m) Crush Resistant Oxygen Tubing</li> <li>• AirLife™ Adult Cushion Nasal Cannula, 4' (1.2m) Crush Resistant Oxygen Tubing</li> </ul>						



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<ul style="list-style-type: none"> <li>• AirLife™ Adult Cushion Nasal Cannula without Oxygen Tubing</li> <li>• AirLife™ Neonate Cushion Nasal Cannula, 7' (2.1m) Crush Resistant Oxygen Tubing</li> <li>• AirLife™ Adult Cushion Nasal Cannula, 14' (4.3m) Crush Resistant Oxygen Tubing</li> <li>• AirLife™ Adult Cushion Nasal Cannula, 14' (4.3m) Crush Resistant Oxygen Tubing, and U/Connect-It Adaptor</li> <li>• AirLife™ Adult Cushion Nasal Cannula, 25' (7.6m) Crush Resistant Oxygen Tubing</li> <li>• AirLife™ Pediatric Cushion Nasal Cannula, 7' (2.1m) Crush Resistant Oxygen Tubing, and U/Connect- It Adapter</li> <li>• AirLife™ Adult Cushion Nasal Cannula, 7' (2.1m) Crush Resistant Oxygen Tubing, and U/Connect-It Adapter</li> </ul>						



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<ul style="list-style-type: none"> <li>• 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</li> <li>• 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</li> <li>• 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</li> <li>• 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</li> <li>• AirLife™ Nasal ETCO2 Cannula, Adult with 7' O2 tube and 7' CO2 tube with female luer connector and 22mm (I.D.) x 6mm (O.D.) adapter</li> </ul>						





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<ul style="list-style-type: none"> <li>• 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</li> <li>• AirLife™ ETCO2 Sample Line, 10' tube with 1 male and 1 female luer connector</li> <li>• AirLife™ ETCO2 Sample Line, 10' tube with 2 male luer connectors</li> <li>• AirLife™ Universal Mouthpiece Polyethylene</li> <li>• AirLife™ Trach Tee Adapter with 22mm O.D. Arms, 15mm I.D. Base</li> <li>• AirLife™ Ventilator Monitoring Adapter Circuit</li> <li>• AirLife™ Trach Tee Oxygenator with Trach Tee (6") 15 cm Flextube, Oxygen Stem Connector, and Thermo-Suction Port</li> <li>• AirLife™ Ventilator Elbow with Suction Port and Cap 22 mm I.D. x 22 mm O.D. Inlet Arm, 15 mm I.D. Base</li> </ul>						



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<ul style="list-style-type: none"> <li>• AirLife™ Trach Mist Unit with Elbow, Trach Elbow with Valves, “Y” with 2 Liter Drainage Bag and Valves Plus Hanger</li> <li>• AirLife™ Trach Mist Unit, “Y” with 2 Liter Drainage Bag and Safety Valve Plus Hanger</li> <li>• AirLife™ Aerosol Drainage Unit, “Y” with 2 Liter Drainage Bag Plus Hanger</li> <li>• AirLife™ Universal Oxygen Nut and Nipple Connection</li> <li>• AirLife™ Oxygen Swivel Connector Male/Male</li> <li>• AirLife™ Oxygen Swivel Connector Male/Female</li> <li>• AirLife™ Water Trap for Oxygen Tubing</li> <li>• AirLife™ Pediatric Oxygen Mask Vinyl, Under the Chin Style, High Concentration, Rebreather Mask (No Valves) with 7' (2.1m) Crush Resistant Oxygen Tubing</li> </ul>						



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<ul style="list-style-type: none"> <li>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</li> <li>AirLife™ Open Oxygen Masks (Medium, Small, Large)</li> </ul>						








# Manufacturer Declaration\_Article 120 Extension\_Vyaire\_Consumables

Final Audit Report

2024-05-17

Created:	2024-05-16
By:	Melissa Souder (melissa.souder@vyaire.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAA8MGKNWS4VMaxGtRA-rznjvQb9NXw7O0w

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-  Document created by Melissa Souder (melissa.souder@vyaire.com)  
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