


AirLife™ Open

Technical Data Sheet



Product Codes and Product Description	AM-1000	AirLife™ Open Mask, Medium				
	AM-1100	AirLife™ Open Mask, Large				
	AM-1200	AirLife™ Open Mask, Small				
General Product Description	<p>AirLife™ Open can effectively deliver oxygen to patients, while remaining comfortable to wear and allowing patients to still undertake normal activities such as drinking or talking. It reduces waste as fewer interfaces are needed. Due to the open design it can be used with an endoscope or bronchoscope.</p>					
Pack factor	25/CA					
EAN/GTIN	AM-1000	EA	10190752146303	AM-1200	EA	10190752146754
		CS	50190752146301		CS	50190752146752
	AM-1100	EA	10190752146747			
		CS	50190752146745			
Intended Use	This product is an oxygen mask used to deliver flows from 1 to 15 liters per minute and flush. It can be used in institutional and transport settings where masks are used to deliver oxygen.					
Instructions for Use	Please refer to the Instructions for Use (IFU).					
Characteristics	<ul style="list-style-type: none"> - 1LPM to 15LPM and flush oxygen flow - Reduces waste and saves time with fewer interfaces - Flow creates a soft curtain of oxygen around nose and mouth - Flow technology is quieter and more comfortable than alternatives - Open design enables talking, drinking and eating - Can be utilised during various oral procedures such as endoscopy/bronchoscopy - Oxygen supply tubing located at the bottom of the mask - Larger internal mask volume accommodates more face morphologies - Comfort split straps provide superior fit and adjustability to reduce skin breakdown concerns 					
Compatibility	Universal oxygen connector					
Shelf Life	36 months					
Regulation	<p>Classifications:</p> <p>Class 1 (US), Class IIa (EU) and Class II (Canada)</p> <p>Products are compliant with REACH.</p>					
Biocompatibility	All materials utilized in this device are biocompatible, meeting skin irritation and sensitization requirements per ISO 10993-10w and cytotoxicity requirements. The device materials met the volatile organic compounds and particulate requirements					
Materials	<p>Face mask Chamber: Flexible PVC (DOTP)</p> <p>Mask manifold: Rigid PVC (DOTP)</p> <p>O₂ tubing: Flexible PVC (DOTP)</p> <p>Universal Connector: Flexible PVC (DOTP)</p> <p>Head Strap: Nylon (82%), Polyurethane (17%), Dye (1%)</p>					
Storage	<p>Temp Low (C°): -20(C°) +/- 2</p> <p>Temp High(C°): 50(C°) +/- 2</p> <p>Storage Humidity Low (%): 15</p> <p>Storage Humidity High (%): 85</p> <p>Material labelled as RX?: Yes</p>					

For global distribution.

© 2021 Vyair. Vyair, the Vyair logo and all other trademarks or registered trademarks are property of Vyair Medical, Inc., or one of its affiliates. Medical devices class I according to Medical Devices Directive 93/42/EEC. Measurements are approximations and may vary. Please read the complete Instructions For Use that come with the devices or follow the instructions on the product labelling. VYR-GBL-2100231 2.0

AirLife™ Open

Technical Data Sheet



GMDN Code	58810
Disposal	Dispose of all materials in accordance with local, state and federal regulations. Decontaminate and dispose of all potentially biohazardous material.
Does it contain PVC, DEHP and/or Latex	PVC materials are not manufactured with DEHP Plasticizer Product is not manufactured with Latex or BPA
Country of Origin	Mexico
Legal Manufacturer	Vyaire Medical
Additional Data	Oxygen flow ratge 1-15 LPM, Plus flush Input pressure 240 kPa to 530 kPa

GLOBAL HEADQUARTERS

Vyaire Medical, Inc.
26125 North Riverwoods Blvd.
Mettawa, IL 60045
USA



Vyaire Medical, Inc.
26125 North Riverwoods Blvd
Mettawa, IL 60045
USA



EMERGO EUROPE
Prinsessegracht 20
2514 AP The Hague
The Netherlands

AUSTRALIAN SPONSOR

Vyaire Medical Pty Ltd
Suite 5.03, Building C
11 Talavera Road
Macquarie Park, NSW 2113
Australia



vyaire.com

For global distribution.

© 2021 Vyaire. Vyaire, the Vyaire logo and all other trademarks or registered trademarks are property of Vyaire Medical, Inc., or one of its affiliates. Medical devices class I according to Medical Devices Directive 93/42/EEC. Measurements are approximations and may vary. Please read the complete Instructions For Use that come with the devices or follow the instructions on the product labelling. VYR-GBL-2100231 2.0