

Technical Data Sheet

Vital Signs® Laryngoscope Blades - Single Use

Product Codes and Product Description	4002VS - Vital Signs® Laryngoscope Blade
General Product Description	The Laryngoscope blades are used to examine the interior of the larynx and for the placement of an endotracheal tube. There are two different main features of the blade: Mac, and Miller. The Miller blade is straight and the side of the flange is reduced to minimize trauma; and the curve at the tip is extended to improve lifting of the epiglottis. The MAC blade is curved and the tip of the blade is compressed into an angle formed by the base of the tongue and the epiglottis, indirectly raising the epiglottis.
Pack factor	20
Intended Use	Intended to visualize a patient's upper airway and aid in placement of a tracheal tube. It is intended for single-use.
Instructions for Use	Please refer to the Instructions for Use (IFU)
Characteristics	These devices are intended for transient at less than sixty minutes as defined by section 1.1 of Annex IX of the Medical Device Directive 93/42/EEC.
Compatibility	The laryngoscope blades are designed to fit any Laryngoscope Handle which is manufactured to EN ISO 7376:2009 standard.
Shelf Life	The Laryngoscope products do not require a "use-by" date because they are sold non-sterile. There are no safety related performance or safety-related characteristics which are likely to deteriorate over time.
Regulation	Laryngoscope blades are class 1 rule by rule 5, transient, invasive, and non-active.
Biocompatibility	All materials are biocompatible, meeting skin irritation and sensitization requirements documents:
Materials	Fiberboard, Oxnilon, Polyethylene, Polyethylene, Ink
Storage	There are no special storage conditions required. Packaging for non sterile devices is intended to protect the product from dust and does not provide a sterile barrier.
GMDN Code	GMDN 46828 – Laryngoscope Blade, Single-Use
Disposal	Dispose of in accordance with national and local authority regulations.
Does it contain PVC, DEHP and/or Latex	DEHP Free PVC Free Latex Free

GLOBAL HEADQUARTERS

Vyaire Medical, Inc.
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FI-00510 Helsinki
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Vyaire Medical Pty Ltd
Level 5, 7 Eden Park Drive
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Technical Data Sheet

Vital Signs® Laryngoscope Blades - Single Use

	BPA Free
Country of Origin	Mexico
Legal Manufacturer	Vyaire Medical Inc., 26125 N. Riverwoods Blvd., Mettawa, IL 60045 USA

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Vital Signs® Laryngoscope Blades - Single Use

Product Codes and Product Description	4002S - Vital Signs® Laryngoscope Blade
General Product Description	The Laryngoscope blades are used to examine the interior of the larynx and for the placement of an endotracheal tube. There are two different main features of the blade: Mac, and Miller. The Miller blade is straight and the side of the flange is reduced to minimize trauma; and the curve at the tip is extended to improve lifting of the epiglottis. The MAC blade is curved and the tip of the blade is compressed into an angle formed by the base of the tongue and the epiglottis, indirectly raising the epiglottis.
Pack factor	20
Intended Use	Intended to visualize a patient's upper airway and aid in placement of a tracheal tube. It is intended for single-use.
Instructions for Use	Please refer to the Instructions for Use (IFU)
Characteristics	These devices are intended for transient at less than sixty minutes as defined by section 1.1 of Annex IX of the Medical Device Directive 93/42/EEC.
Compatibility	The laryngoscope blades are designed to fit any Laryngoscope Handle which is manufactured to EN ISO 7376:2009 standard.
Shelf Life	The Laryngoscope products do not require a "use-by" date because they are sold non-sterile. There are no safety related performance or safety-related characteristics which are likely to deteriorate over time.
Regulation	Laryngoscope blades are class 1 rule by rule 5, transient, invasive, and non-active.
Biocompatibility	All materials are biocompatible, meeting skin irritation and sensitization requirements documents:
Materials	Polyethylene, Nylon blade, acrylic rod, Fiberboard, Ink, Polyethylene, Polyethylene
Storage	There are no special storage conditions required. Packaging for non sterile devices is intended to protect the product from dust and does not provide a sterile barrier.
GMDN Code	GMDN 46828 – Laryngoscope Blade, Single-Use
Disposal	Dispose of in accordance with national and local authority regulations.
Does it contain PVC, DEHP and/or Latex	DEHP Free PVC Free Latex Free

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Vital Signs® Laryngoscope Blades - Single Use

	BPA Free
Country of Origin	Mexico
Legal Manufacturer	Vyaire Medical Inc., 26125 N. Riverwoods Blvd., Mettawa, IL 60045 USA

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Technical Data Sheet

Vital Signs® Laryngoscope Blades - Single Use

Product Codes and Product Description	4003VS - Vital Signs® Laryngoscope Blade
General Product Description	The Laryngoscope blades are used to examine the interior of the larynx and for the placement of an endotracheal tube. There are two different main features of the blade: Mac, and Miller. The Miller blade is straight and the side of the flange is reduced to minimize trauma; and the curve at the tip is extended to improve lifting of the epiglottis. The MAC blade is curved and the tip of the blade is compressed into an angle formed by the base of the tongue and the epiglottis, indirectly raising the epiglottis.
Pack factor	20
Intended Use	Intended to visualize a patient's upper airway and aid in placement of a tracheal tube. It is intended for single-use.
Instructions for Use	Please refer to the Instructions for Use (IFU)
Characteristics	These devices are intended for transient at less than sixty minutes as defined by section 1.1 of Annex IX of the Medical Device Directive 93/42/EEC.
Compatibility	The laryngoscope blades are designed to fit any Laryngoscope Handle which is manufactured to EN ISO 7376:2009 standard.
Shelf Life	The Laryngoscope products do not require a "use-by" date because they are sold non-sterile. There are no safety related performance or safety-related characteristics which are likely to deteriorate over time.
Regulation	Laryngoscope blades are class 1 rule by rule 5, transient, invasive, and non-active.
Biocompatibility	All materials are biocompatible, meeting skin irritation and sensitization requirements documents:
Materials	Oxnilon, Polypropylene, Ink
Storage	There are no special storage conditions required. Packaging for non sterile devices is intended to protect the product from dust and does not provide a sterile barrier.
GMDN Code	GMDN 46828 – Laryngoscope Blade, Single-Use
Disposal	Dispose of in accordance with national and local authority regulations.
Does it contain PVC, DEHP and/or Latex	DEHP Free PVC Free Latex Free

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	BPA Free
Country of Origin	Mexico
Legal Manufacturer	Vyaire Medical Inc., 26125 N. Riverwoods Blvd., Mettawa, IL 60045 USA

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Technical Data Sheet

Exhaust lines and adapters for gas return and scavenging

Product Codes and Product Description	M1031274 - Vital Signs™ Exhaust Line for Gas Return or Scavenging, Disposable, 2m/7ft
General Product Description	The product family consists of exhaust lines and a gas return adapter. Exhaust lines are used for direct exhaust gases from gas monitoring module to gas scavenging system or returning exhaust gases to breathing circuit. Gas return adapter is used for connecting gas exhaust line to breathing circuit to allow gas return. The products of this product family are single-use.
Pack factor	5
Intended Use	Intended to direct exhaust gases from gas monitoring module to gas scavenging system or returning exhaust gases to breathing circuit.
Instructions for Use	Please refer to the Instructions for Use (IFU)
Characteristics	These devices are intended for short term use for more than sixty minutes and less than thirty days as defined by section 1.1 of Annex IX of the Medical Device Directive 93/42/EEC.
Compatibility	M1031274 exhaust line: Compatible with exhaust adapter with male (ISO 594-1) luer connector (e.g adapter M1031273). Compatible with module exhaust male luer connection or scavenging system male luer connection complying with ISO 594-1.
Shelf Life	The products covered by this technical file do not require a “use-by” date because there are no safety-related performance or safety-related characteristics which are likely to deteriorate over time.
Regulation	These products are class IIa by rule 2, short term, non-invasive, and non-active.
Biocompatibility	All materials are biocompatible, meeting skin irritation and sensitization requirements documents:
Materials	PVC, Panlite L-1225Y (polycarbonate)
Storage	There are no special storage conditions required. Packaging for non sterile devices is intended to protect the product from dust and does not provide a sterile barrier.
GMDN Code	45566 Gas-sampling/monitoring respiratory tubing, single-use, non-sterile
Disposal	Dispose of in accordance with national and local authority regulations.
Does it contain PVC, DEHP and/or Latex	Contains DEHP Contains PVC Latex Free BPA Free

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Technical Data Sheet

Exhaust lines and adapters for gas return and scavenging

Country of Origin	Estonia
Legal Manufacturer	Vyaire Finland 320 Oy, Kuortaneenkatu 2, FI-00510 Helsinki, Finland

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Technical Data Sheet

Exhaust lines and adapters for gas return and scavenging

Product Codes and Product Description	M1031273 - Vital Signs™ Gas Return Adapter, 22M-22F, Disposable
General Product Description	The product family consists of exhaust lines and a gas return adapter. Exhaust lines are used for direct exhaust gases from gas monitoring module to gas scavenging system or returning exhaust gases to breathing circuit. Gas return adapter is used for connecting gas exhaust line to breathing circuit to allow gas return. The products of this product family are single-use.
Pack factor	5
Intended Use	Intended to direct exhaust gases from gas monitoring module to gas scavenging system or returning exhaust gases to breathing circuit.
Instructions for Use	Please refer to the Instructions for Use (IFU)
Characteristics	These devices are intended for short term use for more than sixty minutes and less than thirty days as defined by section 1.1 of Annex IX of the Medical Device Directive 93/42/EEC.
Compatibility	M1031273 adapter for gas return: Compatible with ISO 594-1 compliant exhaust line luer female connector and ISO 5356 compliant 22mm male and 22mm female breathing circuit conical connections.
Shelf Life	The products covered by this technical file do not require a “use-by” date because there are no safety-related performance or safety-related characteristics which are likely to deteriorate over time.
Regulation	These products are class IIa by rule 2, short term, non-invasive, and non-active.
Biocompatibility	All materials are biocompatible, meeting skin irritation and sensitization requirements documents:
Materials	PP Borealis RF825MO
Storage	There are no special storage conditions required. Packaging for non sterile devices is intended to protect the product from dust and does not provide a sterile barrier.
GMDN Code	45566 Gas-sampling/monitoring respiratory tubing, single-use, non-sterile
Disposal	Dispose of in accordance with national and local authority regulations.
Does it contain PVC, DEHP and/or Latex	DEHP Free PVC Free Latex Free BPA Free

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Technical Data Sheet

Exhaust lines and adapters for gas return and scavenging

Country of Origin	Taiwan
Legal Manufacturer	Vyaire Finland 320 Oy, Kuortaneenkatu 2, FI-00510 Helsinki, Finland

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