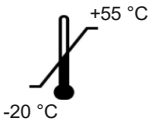
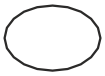
PRODUCT GROUP	Anesthesia Balloons
MANUFACTURER NAME	R VENT Medikal Uretim A.S. Yazibasi Mah. Balkan Cad. İztipsan Apt. No:33/1, Torbalı, 35860- Izmir, Turkey Tel: +90 232 853 9500 E-mail: info@rventmedikal.com
REGULATORY APPROVALS AND CERTIFICATION	ISO 13485 – 31816401 CE Certificate – 2195-MED-1816401
CLASSIFICATION	Disposable Medical Device
	MDD 93/42/EEC Class IIa Rule 2 Annex V, Article 3
CLEANING	The device assembled within ISO 8 Cleanroom.

INTENDED USE	A non-sterile elastomeric reservoir sac intended to store breathing gas during the respiratory cycle. The breathing bag may be on the inspiratory or expiratory limb of a breathing circuit depending on the breathing circuit design. It may also function as a maximum pressure limiting device during spontaneous or manually assisted ventilation. It may be made of conductive or non-conductive material and is typically used in anaesthesia or ventilator breathing circuits. This is a single-use device.
GMDN CODE/DESCRIPTION	**34877** **Breathing circuit bag, single-use** A non-sterile elastomeric reservoir sac intended to store breathing gas during the respiratory cycle. The breathing bag may be on the inspiratory or expiratory limb of a breathing circuit depending on the breathing circuit design. It may also function as a maximum pressure limiting device during spontaneous or manually assisted ventilation. It may be made of conductive or non-conductive material and is typically used in anaesthesia or ventilator breathing circuits. This is a single-use device.
EMDN CODE/DESCRIPTION	**R03020101** Anesthesia Balloons
FEATURES	- Breathing System Accessories - Disposable
SHELF LIFE	5 years from the date of manufacturing. Expiration date and date of production are detailed on the product labelling.
STORAGE CONDITIONS	Temperature: -20°C to +55°C Humidity: 0% to 95% Luminosity: Keep away from direct sunlight
TRANSPORTATION CONDITIONS	Temperature: -20°C to +55°C Humidity: 0% to 95% Luminosity: Keep away from direct sunlight
TECHNICAL SPECIFICATIONS	**Product Name** Anesthesia Bag, Latex, 0.5 lt **Product Code** 6005 **Material** Latex **Volume** 0.5 liter **Capacity** 0.425 lt – 0.575 lt **Colour** Grey **Connection** 22mmM

Product Name	Anesthesia Bag, Latex, 1.0 lt
Product Code	6010
Material	Latex
Volume	1 liter
Capacity	0.85 lt - 1.15 lt
Colour	Grey
Connection	22mmM

	Product Name Anesthesia Bag, Latex, 2.0 lt **Product Code** 6020 **Material** Latex **Volume** 2 liter **Capacity** 1.7 lt – 2.3 lt **Colour** Grey **Connection** 22mmM	
	Product Name Anesthesia Bag, Latex, 3.0 lt **Product Code** 6030 **Material** Latex **Volume** 3 liter **Colour** Grey **Connection** 22mmM	
	Product Name Anesthesia Bag, Latex-free, 0.5 lt **Product Code** 6105 **Material** Neoprene **Volume** 0.5 liter **Capacity** 0.425 lt – 0.575 lt **Colour** Green **Connection** 22mmM	
	Product Name Anesthesia Bag, Latex-free, 1.0 lt **Product Code** 6110 **Material** Neoprene **Volume** 1.0 liter **Capacity** 0.85 lt - 1.15 lt **Colour** Green **Connection** 22mmM	
	Product Name Anesthesia Bag, Latex-free, 2.0 lt **Product Code** 6120 **Material** Neoprene **Volume** 2.0 liter **Capacity** 1.7 lt – 2.3 lt **Colour** Green **Connection** 22mmM	
	Product Name Anesthesia Bag, Latex-free, 3.0 lt **Product Code** 6130 **Material** Neoprene **Volume** 3.0 liter **Colour** Green **Connection** 22mmM	
STERILIZATION STATUS	Non-sterile	
TESTS PERFORMED ON THE PRODUCTS	- Dimensional controls (Gauge, caliper and weight controls) - Routine assembling process controls - Leakage	

PRECAUTIONS

	Consult instruction for use		Do not re-use
	Keep away from sunlight		Do not use if package is opened or damaged
	Latex free		Phthalate free
	Temperature limit		Non-sterile *for non sterile products
	Sterilization method *for sterile products		Do not re-sterilize *for sterile products
	Catalog number		Batch number
	Production date		Manufacturer
	Expiry Date	CE2195	CE Symbol
	Keep Dry		Medical Device
	Unique Device Identifier		Single sterile barrier system

PACKAGING

Pouch: Polyethylene (PE)
Box material: Craft
Box size: 300MM*400MM*240MM

Quantity per box Anesthesia Balloons			
6005	50	6105	50
6010	50	6110	50
6020	70	6120	40
6030	40	6130	40

APPLICABLE STANDARDS

Standard Number	Standard Name
TS EN ISO 5356-1:2015	Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets
TS EN ISO 11135:2014	Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices
TS EN ISO 10993-1:2021	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
TS EN ISO 10993-5:2010	Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity
TS EN ISO 10993-10:2014	Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization
TS EN ISO 10993-12:2021	Biological evaluation of medical devices — Part 12: Sample preparation and reference materials
TS EN ISO 5367:2015	Anaesthetic and respiratory equipment - Breathing sets and connectors
TS EN ISO 13485	Medical devices - Quality management systems - Requirements for regulatory purposes

R VENT Medikal Uretim A.S.
Yazibasi Mah. Balkan Cad. İztipsan Apt.
No:33/1, Torbalı, 35860- Izmir, Turkey

Tel: +90 232 853 9500
E-mail: info@rventmedikal.com

	TS EN ISO 15223-1:2021	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements
	TS EN ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
	TS EN ISO 14644-1:2016	Cleanrooms and associated controlled environments Part 1: Classification of air cleanliness
	TS EN ISO 14971:2020	Medical devices - Application of risk management to medical devices
	TS EN ISO 24971:2021	Medical devices — Guidance on the application of ISO 14971
	TS EN 62366-1: 2015	Medical devices - Part 1: Application of usability engineering to medical devices
	TS EN ISO 10651-4: 2010	Lung ventilators - Part 4: Particular requirements for operator-powered resuscitators
	TS EN 13544-2+A1: 2010	Respiratory therapy equipment - Part 2: Tubing and connectors
	TS EN ISO 27427:2019	Anaesthetic and respiratory equipment - Nebulizing systems and components
	TS EN ISO 5362:2019	Anaesthetic reservoir bags
WASTE METHOD	Local regulations and/or hospital waste management procedures of the relevant country should be followed when disposing of the used products.	
NOTES	-	

R VENT Medikal Uretim A.S.
Yazibasi Mah. Balkan Cad. İztipsan Apt.
No:33/1, Torbalı, 35860- Izmir, Turkey

Tel: +90 232 853 9500
E-mail: info@rventmedikal.com