ANESTHESIA MASKS

AVAILABLE PRODUCTS

PRODUCT	CODE	COLOUR CODE	SIZE	PACKAGING
Anesthesia mask with inflatable cushion	5200/P	Without hook ring	Premature	Single packed. Sold in box of 30 pcs
	5200	WHITE	Child	
	5210	PINK	Infants	
	5220	YELLOW	Boys	
	5230	GREEN	Small adult	
	5240	RED	Medium adult	
	5250	BLUE	Large adult	
	5260	ORANGE	Extralarge adult	

MANUFACTURER (in accordance with DDM 93/42/CEE and subsequently amended and supplemented provided by 2007/47/CEE)

HAROL SRL
Via G. Marcora 53
20097 San Donato Milanese (Italy)

INTENDED USE

The anesthesia mask is used in anesthesia or in the ventilation in combination with tubes or manual resuscitators; it is provided with a cross fastening system for the headgear with colour code.

INDICATIONS FOR CLINICAL ventilation therapy:

cardiogenic pulmonary oedema
acute respiratory insufficiency (IRA)
non-cardiogenic pulmonary oedema
Chest injury
Atelectasis
Post-operative hypoxemia
Asthma
COPD exacerbation
Respiratory assistance pre and post-extubation

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FEATURES AND BENEFIT

Fully transparent mask with inflatable cushion in soft material provided with valve fo the inflatation adjustment without metal parts for use in MRI. Wide range of sizes from the neonatal to the extralarge adult.

WARNINGS AND LIMITATIONS

The device must be used by qualified and trained medical and/or nursing staff.
The clinicians and/or nursing staff must always monitor the patient under ventilation therapy.

MATERIALS

The shell is made of rigid PVC, the cushion of soft PVC and adaptable to the face of the patient, hook ring in PVC of different colour for different size.
The device is not invasive. All materials are used for years in the medical field and to this day do not know each incident reports or adverse reactions attributed to biocompatibility and safety to the same. The materials are tested in accordance with ISO 10993-1. The rule provides that the biocompatibility of materials can be evaluated through rational based on post marketing experience, clinical studies and other information (Ref. ISO 10993-1 par. 3.6 and 3.8)
The device is LATEX FREE and DEPH FREE.
The product is DISPOSABLE, NON STERILE. Do not sterilize. Do not reuse.

QUALITY INSPECTIONS

Quality inspections are extended to the whole productive cycle, controls are made of raw materials acceptance, production controls and final checks before and after packaging the product. Controls can be either visual, dimensional, functional and relative to the packaging.

PRODUCTION METHODS

The devices are made through processes of injection moulding, extrusion, assembly and high frequency welding taking place in Cleanroom validated periodically and subjected to periodic controls and microbiological particle according to UNI EN ISO 14698-1 -2. For each stage of the production process and material handling is guaranteed full traceability through electronic and paper documentation.

PACKAGING, LABELLING AND STORAGE

The device is single packed in polyethylene bag sealed to ensure product clinically clean.
On both the primary and secondary packaging are applied identification labels with product information and symbols complying with UNI CEI EN ISO 15223-1 and annex I paragraph 13.3 of DDM 93/42/EEC and subsequently amended and supplemented provided by 2007/47/EEC.
The maximum duration of the product unopened and stored under normal storage conditions is 5 years.
The expiry date of the product is printed on both the primary and secondary packaging.
Do not use if package is damaged or perforated.
At present there are no contraindications for exposing devices to natural or artificial light.
If stored and used according to the instructions provided, the materials do not alter their physical and chemical stability.
No one knows the physical-chemical incompatibility towards substances with which they could enter into contact during the intended use by the manufacturer.
Maximum storage and transport temperature -20° C to +50° C
The device must be disposed in accordance with the laws of hospital waste.

CERTIFICATION AND HARMONIZED RULES

The company's quality system is certified ISO 13485-2016 - certificate no. 9124 HRL2. The product complies with the requirements of Annex I of Directive 93/42/EEC and subsequent amendments provided by 2007/47/ EEC.

The manufacturing complies with the requirements of Annex V of the MDD 93/42/EEC and subsequent amendments provided by 2007/47/EEC as certified by IMQ - Notified Body No. 0051

Certificate No. 2033/MDD.

The product is classified in class IIa according to the classification rules of Annex IX of the MDD 93/42/EEC and subsequent amendments provided by 2007/47/EEC.

Harmonized rules: ISO 5356-1, ISO 10993, UNI CEI EN ISO 15223-1, UNI CEI EN 1041.