HAROL

CPAP KIT WITH MASK

AVAILABLE PRODUCTS

PRODUCT	CODE	SIZE	PACKAGING
CPAP KIT with mask, tube,adjustable PEEP valve and headgear	1520-180-255	EXTRA LARGE	SINGLE PACKED. SOLD IN BOX OF 5 PIECES
	1520-180-256	LARGE	
	1520-180-257	MEDIUM	
	1520-180-251	SMALL	

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 (Italia)

INTENDED USE
The kit is intended to be used for non invasive ventilation CPAP in hospital environment.

INDICATIONS FOR CLINICAL VENTILATION THERAPY:
Cardiogenic pulmonary oedema
Acute respiratory insufficiency (IRA)
Non-cardiogenic pulmonary oedema (A.L.I. - ARDS)
Chest injury
Atelectasis

Digitally signed by Moraru Grigore
Date: 2023.09.17 10:08:02 EEST
Reason: MoldSign Signature
Location: Moldova

CERTIFICATION

The product is an assembled kit in accordance with art. 12 of Directive 93/42/CEE. The components are fully compatible with each other and intended for use for which it is intended by the manufacturer.
The product is classified in class IIa according to the classification rules of Annex IX of the MDD 93/42/CEE.
The mask, the headgear, the PEEP valve and the tube are certified by IMQ - Notified Body n. 0051.
Certificate n° 2033/MDD.
Shelf life of the products is 5 years. The shelf life may be lower based on the expiry date of the individual components.

Below you will find the technical data sheets with details of individual components.

CPAP MASK

AVAILABLE PRODUCTS

PRODUCT	CODE	SIZE	PACKAGING
Twin port CPAP mask with inflatable cushion	9016/XL	EXTRALARGE	SINGLE PACKED
	9016/L	LARGE	SINGLE PACKED
	9016/M	MEDIUM	SINGLE PACKED
	9016/S	SMALL	SINGLE PACKED

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 mask is used in CPAP therapy for treatment with the mixture of air / oxygen, it is provided with coupling system for fixing on the patient through headgear.

INDICATIONS FOR CLINICAL ventilation therapy:

cardiogenic pulmonary oedema
acute respiratory insufficiency (IRA)
non-cardiogenic pulmonary oedema (A.L.I. – A.R.D.S)
Chest injury
Atelectasis
Post-operative hypoxemia
Asthma
COPD exacerbation
Respiratory assistance pre and post-extubation

FEATURES AND BENEFIT

Fully transparent mask with inflatable cushion in very soft material provided with a valve for the adjustment of inflation without metal parts for use in MRI. The mask is equipped with valves of inhalation and exhalation for the connection of the PEEP valve and inlet flow tube.
The mask has a 22M connection for direct connection of the corrugated tube without the need of any adapter.
The mask is also provided with an anti-suffocation valve which permits the patient, in case of no flow, to inhale ambient air.

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 in soft PVC so to be adaptable to the patient's face; the valve and the membranes are made of soft PVC.
The product 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 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 product 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 of in accordance with current laws.

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 required by 2007/47/EEC.
Harmonized rules: ISO 10993, UNI CEI EN ISO 15223-1, UNI CEI EN 1041.

DISPOSABLE TUBES

AVAILABLE PRODUCTS

PRODUCT	CODE	LENGTH	PACKAGING
Breathing PE tube in various lengths	1520-30	30 cm.	Single unit. Sold in box of 10 pcs
	1520-60	60 cm.	
	1520-80	80 cm	
	1520-100	100 cm	
	1520-120	120 cm.	
	1520-150	150 cm.	
	1520-180	180 cm.	

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 (Italia)

INTENDED USE
The tube is used in combination with masks and connectors for the creation of ventilation circuits, for anesthesia, intensive care and CPAP/NIV therapy

INDICATIONS FOR CLINICAL

cardiogenic pulmonary oedema
acute respiratory insufficiency (IRA)

non-cardiogenic pulmonary oedema (A.L.I. – ARDS)
Chest injury
Atelectasis
Post-operative hypoxemia
Asthma
COPD exacerbation
Respiratory assistance pre and post-extubation

FEATURES AND BENEFIT

The tube is sold in pieces already cut in difference sizes, internally and externally corrugated and equipped with 22 mm and fitting.

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 tube is made of PE. 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.
The device 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 products are made through processes of injection moulding, extrusion, assembly 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 product is single packed in polyethylene bag sealed to ensure product clinically clean. 10 pcs are packaged in one carton.
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 local regulations.

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.

HAROL

DISPOSABLE
ADJUSTABLE PEEP VALVE

AVAILABLE PRODUCTS

PRODUCT	CODE	PACKAGING
Disposable adjustable PEEP valve	9000/22	Single package. Box of 10 pcs.

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 (Italia)

INTENDED USE

The PEEP valve is used in CPAP therapy in combination with masks or helmets. It produces a positive end-expiratory pressure adjustable between 0 and 20 cm H_2O suitable for CPAP therapy.

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

FEATURES AND BENEFITS

The PEEP valve allow to keep the positive pressure value costant during continuos flow therapy even when the flow itself varies, therefore it is flow independent. Pressure is adjusted by turning the knob, turning the knob clockwise increases the pressure, turning it counterclockwise decreases. On the valve there is a graduate scale that allows to set the desired PEEP value in the range between 5 and 20 cm. of H_2O. The use of a pressure manometer is recommende to check the correct pressure value. The valve has 30M and 22M connection in according to ISO 5356-1, do not need any adapter fitting. It is compatible with all CPAP masks and helmets. The valve plate and the radial

slots reduce the noise to a minimum, furthermore the plate acts as a non-rebreathing valve when the pressure drops below the nominal value.

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 body of the valve is in PP, stainless steel spring, the valve plate is in LPDE and the knob is in ABS.
The product 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 DEHP 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 products are made through processes of injection moulding, extrusion, assembly 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 product is single packed in polyethylene bag sealed to ensure product clinically clean. 10 pcs are packaged in a white cardboard.
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 of in accordance with current laws.

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 standars: ISO 5356-1, ISO 10993, UNI CEI EN ISO 15223-1, UN

HAROL

DISPOSABLE
HEADGEAR WITH STRAPS

AVAILABLE PRODUCTS

PRODUCT	CODE	SIZE	PACKAGING
Disposable Headgear	9019	ADULT	Single unit
	9019/1	PEDIATRIC	

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 (Italia)

INTENDED USE
The headgear is used together with masks provided with metal or plastic fastening system.

FEATURES AND BENEFITS
The headgear is the most suitable device for fixing the mask to the patient's head. The part resting on the nape is made of soft silicone with very low elastic thickness and it conforms to the patient's head without unpleasant hair tearing

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 product is made of die-cutted silicone sheets
The device is LATEX FREE and DEHP FREE
The device is DISPOSABLE – Do not sterilize

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 products are made through processes of injection moulding, extrusion, assembly 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 product 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 of in accordance with current laws.

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.