COMMERCIAL TECHNICAL DATA SHEET

ORONASAL MASK FOR NON-INVASIVE VENTILATION

Vented version with safety valve FOR SINGLE LIMB VENTILATORS

CODE	DESCRIPTION	CND	Repertory number
700/10614	Oronasal Mask for N.I.M.V., ”Non Vented” size S	R03010105	1359508/R
700/10615	Oronasal Mask for N.I.M.V., Non Vented” size M		
700/10616	Oronasal Mask for N.I.M.V., Non Vented” size L/XL		
700/10624	Oronasal Mask for C.P.A.P, ”Vented” size S		
700/10625	Oronasal Mask for C.P.A.P, ”Vented” size M		
700/10626	Oronasal Mask for C.P.A.P, ”Vented” size L/XL		

MANUFACTURER: DIMAR s.r.l. - Medolla - (MO) Italy

Digitally signed by Rusu Ghenadie
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Reason: MoldSign Signature
Location: Moldova

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DESCRIPTION: Oral-nasal mask for non-invasive mechanical ventilation in CPAP / BiPAP / NIPPV techniques, single-patient, made of rigid, transparent, non-deformable, non-toxic and biocompatible plastic material.
Equipped with a non-toxic, soft, atraumatic medical silicone flange, shaped to ensure a high pneumatic seal and minimize the risk of pressure injuries, adapting to the patient's facial profile. During the treatment phase, the membrane of the support cushion stretches like a sail, creating an extensive contact surface with the face, allowing it to be held, without the need to exert excessive traction on the fixing neck. The mask is equipped with a flexible and soft front spacer support that allows you to adjust the pressure exerted by the mask on the back of the nose, guaranteeing a perfect seal and reducing the risk of decubitus, wounds or ulcers at the points of contact.
Equipped with neck mask-holder in breathable, non-traumatic, adjustable and complete with n. 4 clip attachment points for fastening with a "quick" hooking / release system that allows for quick and safe positioning of the mask on the patient's face and easy and quick removal.
Equipped with a 360 ° swivel elbow fitting with 22 mm connection. ISO and n. 1 or 2 sockets for pressure / FiO2 / ETCO2 monitoring or oxygen connection with plug closure.
Thanks to the manageability, the completeness of the device and the proven efficiency, the system is fast, practical and effective.
Compatible with both volumetric (“Non Vented” / two-pipe) and pressometric (“Vented” / single-pipe) fans. In the “Vented” model there is an anti-suffocation safety valve and CO2 exhalation holes.
The device thus composed, ready for use, is of reduced weight, small footprint and easy to use. It is packaged in a single bag with pre-cut and arrows that makes opening easy and quick even in emergency situations.
The materials and technologies used, combined with the accuracy of construction, guarantee the achievement of a particularly soft and comfortable product, equipped with ergonomic characteristics and designed in order to meet clinical needs in order to be easy to use for operators and comfortable for the patient.
The combination and quality of materials make it particularly resistant to use and comfortable for the patient, while also ensuring safe and stable fixation. The ergonomic features defined in the design phase facilitate cleaning and disinfection maneuvers.
Available size range: S (Small) - M (Medium) - L / XL (Large / ExtraLarge).

MATERIALS: Mask body in polycarbonate and face and front support cushion in medical grade silicone. Fabric core. The contact with the patient's face is made of silicone, known for softness, biocompatibility and resistance to bacteria.

SIZES AVAILABLE: see chart.

FREE OF NATURAL LATEX AND PHTHALATES

CONNECTION: 22M / 22F fitting compliant with UNI EN ISO 5356-1.

INTENDED USE: in Resuscitation and Intensive Care in N.P.P.V., BIPAP techniques and for weaning from respirator of patients intubated and subjected to mechanical ventilation.
For the administration of air-oxygen gaseous mixtures in positive pressure in the wards of patients with respiratory diseases and in home treatment. The patient must always be monitored with pulse oximeter systems having active alarms.

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USE: SINGLE-PATIENT

DISINFECTION: the disinfection instructions are given in the instructions for use.

STERILITY: Supplied in single NON-STERILE packaging.

STERILIZATION: Possible through Ethylene Oxide with method validated according to UNI EN ISO 11135-1: 2014.

REGULATORY REQUIREMENTS: the device belongs to class IIa, as provided for in Annex IX of the EEC Directive 93/42 on Medical Devices and the adjustments required by 2007/47 / EEC.

TESTS: carried out on 100% of the products with issue of a certificate of release
All the materials and components used for the realization of the final product are subjected to an acceptance check on the basis of control plans that define the criteria.
Production is carried out by highly qualified personnel in the internal department in a controlled environment of ISO 8 class. The product is also subjected to a process control during all the expected assembly phases and to a final control. All the above checks are recorded in the relative forms. The final batch release is carried out by the Quality Assurance Manager.

SINGLE PACKAGING: 1 piece.

MINIMUM PACKAGING: the product is individually packaged in transparent polyethylene bags with pre-cut and arrows that facilitate single-tear opening of the same even in emergency conditions; A label is applied to each envelope clearly stating all the information necessary to identify the model and size contained and in particular:
- Commercial name of the product / description;
- Size / measure;
- Code / batch / production date / expiry date / quantity;
- Symbol related to Ethylene Oxide sterility (if applicable);
- CE mark;
- Manufacturer's data;
- Possible image of the inserted product;
- Symbols of: no latex (if applicable) / disposable (if applicable) / no phthalates (if applicable) / presence of instructions for use.

The primary packaging bag, being made of a single material such as low density polyethylene and not coupled with medical paper and polythene, facilitates disposal operations, allowing the operator to directly differentiate the wrapping, without having to separate the materials.
The bags used for the primary packaging of the products are made of medical material which guarantees the preservation of the product from possible external contamination. The packaging material used is latex-free.
Characterized by the presence of a pre-cut which makes tearing and consequent extraction of the medical device quick, even in emergency conditions.
Multiple pack of 10 pieces, containing an instruction for use.
The cardboard boxes used are resistant and easily stackable. The information necessary to identify the model and size are also shown on the "front" side of the box, allowing product recognition even if the boxes are overlapped.

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VALIDITY OF THE PRODUCT: 5 years from the date of production.

STORAGE METHOD: Recommended storage temperature: from 0 ° C. to 60 ° C. (32 ° ÷ 140 ° F.). Keep in a clean place.

DISPOSAL PROVISIONS: The device must be disposed of according to the disposal procedures in force for hospital waste.