PALLONE RIANIMATORE
RESUSCITATOR BAG
INSUFFLATEUR DE REANIMATION
WIEDERBELEBUNGSBALLON
BALON DE REANIMACION

MANUALE D'USO E MANUTENZIONE
USE AND MAINTENANCE BOOK
INSTRUCTIONS DE FONCIONNEMENT ET ENTRETIEN
BETRIEBS UND WARTUNGS ANWEISUNGEN
MANUAL DE USO Y MANTENIMIENTO

ATTENZIONE: Gli operatori devono leggere e capire completamente questo manuale prima di utilizzare il prodotto.
ATTENTION: *The operators must carefully read and completely understand the present manual before using the product.*
AVIS: Les opérateurs doivent lire et bien comprendre ce manuel avant d'utiliser le produit.
ACHTUNG: *Die Bediener müssen vorher dieses Handbuch gelesen und verstanden haben, bevor sie das Produkt benutzen.*
ATENCIÓN: Los operadores tienen que leer y entender completamente este manual antes de utilizar el producto.

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FEATURES

The balloon-type resuscitator is a medical device that is ideal for first aid purposes, as it enables fast, effective intervention in cases where the patient is struck by breathing problems. It can be used with every model of resuscitation mask.
The balloon-type resuscitator consists of a sack, a mask connection unit (containing a membrane outlet), and an inlet valve. The membrane outlet opens during insufflation, exercising slight pressure, and closes when the patient exhales, thereby preventing the patient from breathing into the sack.
All balloon parts, except the **disposable** models, can be easily sterilized in a **steam autoclave** at 121ºC and then reused.

The bag has been designed to be used in hospital or private facilities with the aim of permitting the storing and/or the shifting of air or air/oxygen mixture for the resuscitation of patients with respiratory failure using proper reanimation masks.

In any case the manufacturer does not assume any responsability for improper uses of the product under the conditions listed below:

Connecting the bag to improper devices which could interfere with the working of the bag;
Using the bag for inhalation therapies;
Introducing changes or tampering not authorized by GIMA;
Violating the rules specified on the information report.

PRESCRIPTIONS

The product is to be used solely by qualified medical personnel with specific experience in medical treatment, so as to ensure patients the highest level of safety.
Since the product is made of corrosion-proof materials suitable for the enviromental conditions foreseen for its normal use, does not require special care, however it is necessary to store it in a closed place making sure that is protected from dust and dirt to assure its hygenic conditions. Moreover, it is recommended to store the product in a place which can be reached easily by the personnel in case of necessity.

Check the product periodically, especially their hygienic conditions of the storage place in order to assure the maximum efficiency and safety when used.

UNPACKING

Always remember that packing elements (paper, cellophane, stitches, adhesive tape, etc.) can cut and/or hurt if they are not carefully handled.
They shall be removed with adequate means and shall not be left at the mercy of irresponsible persons; the same is valid for tools used to remove packages (scissors, knives, etc.).

After opening the packages, first of all it is necessary to check all pieces and parts composing the product. Check that they are all present and in perfect conditions.
We should also remind you that, as the product is packed in non-sterile packaging, before using it for the first time, it must be washed under running water, using neutral, sterilized soap.

To clean and reassemble the product, use sterile latex gloves.

FUNCTIONING

For a correct use the bag must be connected to the mask using the proper tube fitting on the linkage group, fig. 1.
Then start the reanimation pressing the insufflator alternatively to transfer air or air/oxygen mixtures to the patient, according to the medical indications, making sure that the mask adheres to the patient's face, fig. 2.

During use do not turn the air influx zone of the bag to areas contaminated by gas, dust or smoke. If the patient starts vomiting or bleeding from the nose, remove the mask and follow the prescribed medical emergency procedures.

MAINTENANCE

The following maintenance procedures refer solely to reusable balloon parts; ***disposable*** *models must be disposed of after being used and may not,* ***under any circumstances****, be reused.*

After every use, the product must be fully disassembled and carefully washed using water and neutral soap; then, after it has dried thoroughly, the product must be **sterilized**. It may be either cold-sterilized or sterilized in a steam autoclave at 121ºC (with non-enveloped cycle).
Once sterile, the product must be kept in a closed space, so as to avoid any contact with dust or dirt, and to ensure the necessary hygienic conditions.

Should the product come into contact with non-sterile agents, it will no longer ensure the necessary hygienic conditions: as a result, cleaning and sterilizing procedures must be carried out once again.

GUARANTEE

Thank you for having acquired our product.
This product meets the most stringent requirements regarding the selection of quality manufacturing materials and also the final control. The product has a 12-month warranty, valid from the date it is delivered by GIMA.
During the guarantee period free repair and/or replacement of any defective parts due to faulty manufacture will be given, labour, postal, transport and packaging charges etc. are not included. The guarantee therefore excludes components subject to wear and tear such as parts in rubber or PVC, doppler probes, SpO_2 sensors, lamps, batteries, electrodes, handpieces, washers and packings, resistances, etc. No compensation will be given for loss of use of the product.
Furthermore replacement or repairs effected during the guarantee period do not lengthen the duration of the guarantee.

This guarantee is void in the event of: repairs effected by unauthorised persons or with spare parts not approved by GIMA, damage or defects caused by negligence, blows, abnormal use of the appliance or faulty installation.

The guarantee will be invalidated if the registration number has been removed, cancelled or altered.
Faulty appliances must be returned only to the retailer where the item was bought. Any item dispatched directly to us will be refused.

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GIMA
PROFESSIONAL MEDICAL PRODUCTS

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DICHIARAZIONE DI CONFORMITA':

Ai sensi della Direttiva 93/42/CEE del Consiglio del 14 Giugno 1993 concernente i dispositivi medici recepita in Italia con D.Lgs. del 24 Febbraio 1997 n. 46 e successive modificazioni

DECLARATION OF CONFORMITY:

According to the 93/42/EEC Council Directive concerning Medical Devices

Dichiariamo sotto nostra responsabilità che i seguenti prodotti:
We declare under our own responsibility that the following products

PALLONE RIANIMATORE
RESUSCITATOR BAG
Cod. 34230 - 34231 - 34232 - 34233 - 34240 - 34241 - 34242

sono conformi ai requisiti essenziali della Direttiva Comunitaria
93/42/CEE-allegato VII (classe I)
meet the essential provisions of the Council Directive
93/42/CEE-annex-VII (class I)

GIMA S.p.A.
Rappresentante Legale
Dr. Giulio Manzoni

GIMA S.p.A
Assicuratore Qualità
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