

PVC Manual Resuscitator

It is applicable to the occasions of cardiopulmonary resuscitation and respiratory first aid at work. It is especially suitable for asphyxia, dyspnea or the need to increase the oxygen supply. It is easy to use, less pain, less complications, easy to carry, and can be immediately ventilated with or without oxygen source.

Conventional configuration: PVC resuscitation bag, air bag, oxygen tube, PVC anesthesia mask, instructions manual.

Optional accessories: oropharyngeal airway (edge type and central type), opener, PEEP valve.

Packing method: PP box, paper box, PE bag.

1. The product uses medical grade PVC. It is non-toxic and non-irritating.
2. The mask is made of PVC material, The air cushion contour of the mask fits the human face shape and provides good sealing effect.
3. The product specification is complete and is disposable



Item No.	Patient Size
PMR-L	Adult
PMR-M	Pediatric
PMR-S	Infant

Silicone Manual Resuscitator



It is especially suitable for asphyxia, dyspnea or the need to increase the oxygen supply. It is easy to use, less pain, less complications, easy to carry, and can be immediately ventilated with or without oxygen source.

Conventional configuration: silicone resuscitation bag, air bag, oxygen tube, silicone anesthesia mask, instructions manual.

Optional 2 with 2 pieces: oropharyngeal airway (edge type and central type), opener, PEEP valve.

Packing method: PP box. Paper box, PE bag.

1. The product uses medical grade silicone, which is non-toxic, non-irritating and non-allergic.
2. The product specification is complete, and it is reused for 20 times.



Item No.	Patient Size
SMR-L	Adult
SMR-M	Pediatric
SMR-S	Infant



Product Service

Confirmation Statement on validity of EC Certificate (MDD)
pursuant to Directive 93/42/EEC concerning medical devices

No. GCQ 086250 0021 Rev. 00

Manufacturer: **Ningbo Luke Medical Devices Co., Ltd.**
Gujiayan, Yangming Road
315400 Yuyao City, Zhejiang Province
PEOPLE'S REPUBLIC OF CHINA

This Confirmation Statement is only valid in combination with the following EC Certificate (MDD): **G2 086250 0018 Rev. 01**

This Confirmation Statement confirms the validity of the aforementioned EC Certificate (MDD). It considers clarification of scope statements, scope reductions and changes to the manufacturer data initiated 26 May 2021 or later. The conditions laid down in Article 120 (3) of Regulation (EU) 2017/745 on medical devices for placing devices on the market and putting into service apply. For details and confirmation statement validity see: www.tuvsud.com/ps-cert?q=cert:GCQ_086250_0021_Rev_00

Report No.: SH2265101

Valid until: 2024-05-26

Issue Date: 2023-05-15

Christoph Dicks
Head of Certification/Notified Body

Confirmation Statement on validity of EC Certificate (MDD)
pursuant to Directive 93/42/EEC concerning medical devices

No. GCQ 086250 0021 Rev. 00

Product Category(ies): Laryngeal Mask Airways,
Stomach Tubes, Drainage Tubes,
Endotracheal Tubes, Oxygen Masks,
Suction Catheters, Nasal Oxygen Cannulas,
Breathing Circuits,
Heat and Moisture Exchangers,
Breathing System Filters,
Manual Resuscitators,
Wound Drainage Systems,
Double Lumen Endobronchial Tubes,
Disposable Endobronchial Blocker Tubes,
Anesthesia Masks, Catheter Mounts,
Suction Tubing with Yankauer Handle,
Nebulizer Masks, Tracheostomy Tubes.

**Description of
Change:**

Reduction of product category(ies):
Infusion Sets with Precision Filters for Single-Use,
Urinary Catheterization Collection Kits, Single-Use
Anesthesia Kits

Reduction of facility: CANACK TECHNOLOGY LTD.
Room 1308-2, Building A, Huaxing Times Square, No.
478 Wensan Road, Xihu District 310007 Hangzhou City,
Zhejiang Province, PEOPLE'S REPUBLIC OF CHINA



Product Service

Declarație de confirmare a valabilității Certificatului CE (MDD)

în baza Directivei 93/42/CEE privind dispozitivele medicale

Nr. GCQ 086250 0021 Rev. 00

Producător:

Ningbo Luke Medical Devices Co., Ltd.

Gujiayan, Yangming Road
315400 Yuyao City, Zhejiang Province
REPUBLICA POPULARĂ CHINEZĂ

Această declarație de confirmare este valabilă numai în combinație cu următoarele
Certificat CE (MDD):

G2 086250 0018 Rev. 01

Această declarație de confirmare confirmă valabilitatea Certificatului CE (MDD) menționat mai sus.

Se ia în considerare clarificarea declarațiilor privind domeniul de aplicare, reducerile domeniului și modificările la datele producătorului inițiate la 26 mai 2021 sau ulterior.

Se aplică condițiile prevăzute la articolul 120 alineatul (3) din Regulamentul (UE) 2017/745 privind dispozitivele medicale pentru introducerea pe piață și punerea în funcțiune a dispozitivelor. Pentru detalii și valabilitatea declarației de confirmare accesați:
[www.tuvsud.com/ps-cert?q=cert:GCQ 086250 0021 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:GCQ_086250_0021_Rev.00)

Raport Nr.:

SH2265101

Valabil până la:

26-05-2024

Data emiterii: 2023-05-15

Christoph Dicks
Șef pentru certificare/Organism notificat
/Semnătura indescifrabilă/

Declarație de confirmare a valabilității Certificatului CE (MDD)

în baza Directivei 93/42/CEE privind dispozitivele medicale

Nr. GCQ 086250 0021 Rev. 00

Categoriile de produse: Mască laringială căi respiratorii,
Tuburi stomac, tuburi de drenaj,
Tuburi endotraheale, măști de oxigen,
catetere de aspirație, canule nazale de
oxigen, circuite respiratorii,
schimbătoare de căldură și
umiditate, filter pentru sistemul
respirator, aparate de
resuscitare manuale,
sisteme de drenaje pentru plăgi,
tuburi endotraheale duble iluminate, Tuburi de
blocare endobronhială de unică folosință,
Măști de anestezie, suporturi cateter, tuburi de
aspirație cu mâner Yankauer, Măști de
nebulizator, tuburi de traheostomie.

Descrierea modificării:

Reducerea categoriilor de produse:

Seturi de perfuzie cu filtre de precizie de unică
folosință, truse de colectare pentru cateterism
urinar, truse de anestezie de unică folosință

Facilitatea de reducere: CANACK TECHNOLOGY LTD.
Room 1308-2, Building A, Huaxing Times Square, No.
478 Wensan Road, Xihu District 310007 Hangzhou City,
Zhejiang Province, R.P. CHINEZĂ

Subsemnatul **CIUHU BOGDAN CONSTANTIN**,

traducător autorizat cu nr. 7319/2002 certific exactitatea traducerii cu textul documentului, redactat
în limba **engleză** și vizat de mine.

Traducător Autorizat
CIUHU BOGDAN CONSTANTIN
Spaniolă, Engleză
Aut. M.J. 7319/2002

