

<b>DATI TECNICI / technical sheet</b>	<b>PALLONE RIANIMAZIONE SILICONE</b>
<b>CE0434</b>	<b>silicone resuscitator bags</b>

autoclavabile / autoclavable

93/42/CE

2007/47/CE

1	VALVOLA PAZIENTE <i>patient valve</i>	policarbonato <i>polycarbonate</i>
2	CORPO CENTRALE <i>Central body</i>	SILICONE <i>silicone</i>
3	VALVOLA SOVRAPPRESSIONE <i>pop-off valve</i>	policarbonatosilicone ,acciaio <i>polycarbonate,silicone ,steel</i>
4	CONNETTORI OSSIGENO E RESERVOIR <i>oxygen and reservoir connectors</i>	policarbonato <i>polycarbonate</i>
5	CONNETTORE PER MASCHERA <i>mask connector</i>	policarbonato <i>polycarbonate</i>
6	MASCHERA <i>mask</i>	silicone (policarbonato) <i>silicone (polycarbonate)</i>
7	RESERVOIR <i>reservoir</i>	EVA, PP <i>EVA, PP</i>
8	TUBO OSSIGENO <i>oxygen tube</i>	PVC <i>PVC</i>



**peso/weight - volume pallone /Resuscitator volume :**

600g 1630 ml

410 g 680 ml

350 g 340 ml

**Dispositivo Medico classe I**  
*medical devices class I*

**cod. PRM062 adulti / adults**  
**cod. PRM063 pediatrico / child**  
**cod. PRM064 neonati / infant**



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**volume reservoir/bag reservoir volume :**  
PRM064 :1600 ml      PRM063: 1600 ml

PRM062: 2000 ml



contenitore in PP/PP hard case

# Technical Data Sheet

## Silicone Manual Resuscitator

The manual resuscitator is intended for pulmonary resuscitation.

- NON-STERILE
- Latex Free



### Material:

Device component	Material
connector	Polycarbonate
Patient valve	Polycarbonate
Pressure Limiting valve	Polycarbonate , silicone ,steel
Resuscitation bag	Silicone
Intake valve	Polycarbonate
valve disk	Silicone
Reservoir bag	EVA , PP
Oxygen tubing	PVC
Face mask	Silicone, (Polycarbonate)

### Specifications:

	Infant	Pediatric	Adult
Body weight	≤10 kg	10kg~33kg	≥33kg
Stroke volume	150 ml	350 ml	800 ml
Resuscitator volume	340ml/280ml	680ml	1630ml
Dimensions(Lenght×Diameter )	225×85mm	262×105mm	325×132mm
Pressure limiting valve	40 cmH2O	40 cmH2O	60 cmH2O
Dead space(patient valve)	7 ml	7ml	7 ml
Inspiratory resistance	<5 cmH2O (at 50 L/min)		
Expiratory resistance	<5 cmH2O (at 50 L/min)		
Bag reservoir volume	1600 ml	1600 ml	2000 ml
Patient connector	ISO Ø22 & 15 mm		
Recommended Operating temperature: -18 °C ~ +50 °C			
Storage	-40 °C ~ +60 °C		
Standard	ISO10651-4, ISO10993-1,-5,-10		

**Certification :** ENISO 13485: 2016, CE ( directive 93/42/EEC )



# Technical Data Sheet

## Silicone Mask



### Item Number and Specifications:

Silicone mask for neonate (0#) with 15mm male adapter

Silicone mask for infant (1#) with 15mm male adapter

Silicone mask for pediatric (2#) with 22mm female adapter

Silicone mask for adult(3#) with 22mm female adapter

Silicone mask for adult(4#) with 22mm female adapter

Silicone mask for adult(5#) with 22mm female adapter

Silicone &PC mask for adult(3#) with 22mm female adapter

Silicone &PC mask for adult(4#) with 22mm female adapter

Silicone &PC mask for adult(5#) with 22mm female adapter

### Features:

Latex-free

Maintaining airtight seal

Silicone mask can be autoclaved repeatedly up to 121 °C

### Regulation:

Meet to Council Directive MDD/93/42/EEC concerning Medical Devices

**Certification** : ISO 13485: 2016, CE ( directive 93/42/EEC )