康勃医疗
Compower® COMPOWER MEDICAL

Solid Silicone Manual Resuscitator

Adult

Model and specification: SSI-01/S

- Resuscitator bag 1500ml;
- Silicone mask 4#;
- 2000ml reservior bag;
- Oxygen tube 2.1M;
- Patient connector: 15/22mm;
- Pressure limiting valve: 60 cmH2O;

Pediatric

Model and specification: SSI-02/S

- Resuscitator bag 550ml;
- Silicone mask - 2#;
- 1600ml reservior bag;
- Oxygen tube 2.1M;
- Patient connector: 15/22mm;
- Pressure limiting valve: 40 cmH2O;

Infant

Model and specification: SSI-03/S1

- Resuscitator bag 280ml;
- Silicone mask -1#;
- 1600ml reservior bag;
- Oxygen tube 2.1M;
- Patient connector: 15/22mm;
- Pressure limiting valve: 40 cmH2O;

Digitally signed by Furculiță Andrei
Date: 2023.05.30 00:59:39 EEST
Reason: MoldSign Signature
Location: Moldova

Registration Certificate No. : Min Xie Zhu Zhun No.20152080158

Scope of application: Used for artificial respiration for people with respiratory disorder.

Parts:The product consists of a mask, resuscitator bag, patient valve, intake valve, reservior bag and oxygen tube, mouth opener and oropharyngeal airway. The finished product is non-sterile.

CPR mask

Foldable air cushion mask with oxygen port.

Suitable for Adult and child size.
Elastic head strap.
Hard case comes in assorted colors.

Registration Certificate No. : Min Xie Zhu Zhun No.20172080112
Scope of application: used for emergency rescue of patients with breathing disorders.
Parts: It is composed of non-rebreathing valve group (including non-rebreathing valve top cover, filter cotton, non-rebreathing valve disc, non-rebreathing valve bot cover), mask cover, oxygen port, oxygen port cover, air-cushion and elastic head strap, the material of the air-cushion and mask cover are PVC, the material of the filter cotton is PP, the material of the non-rebreathing valve top cover and the non-rebreathing valve bot cover are butadiene-styrene copolymer. Non-sterile.

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q6 063744 0017 Rev. 01

Holder of Certificate: **Xiamen Compower Medical Tech. Co., Ltd.**
Unit 301, No.16, Xianghong Road
Xiang'an Torch Industrial Zone
361101 Xiamen
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Xiamen Compower Medical Tech. Co., Ltd.
Unit 301, No.16, Xianghong Road, Xiang'an Torch Industrial Zone,
361101 Xiamen, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: **Production and Distribution of Manual Resuscitators with Accessories, Resuscitation Mask, Pneumatic Splint, Continuous Positive Airway Pressure Mask/Non-invasive Ventilation Mask, Simple Oxygen Mask, Venturi Mask, Non-Rebreathing Mask, Aerosol Mask w/Nebulizer, Breathing Circuit,Anesthesia Circuit, Nose Clip, Anesthesia Mask, Breathing Filter for Single Use**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH1917614

Valid from: 2019-10-01
Valid until: 2022-09-30

Date, 2019-08-26

Stefan Preiß
Head of Certification/Notified Body

TÜV

A4 / 07.17

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
ZLG-BS-244.10.08

Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 063744 0018 Rev. 02

Manufacturer:

Xiamen Compower Medical Tech. Co., Ltd.
Unit 301, No.16, Xianghong Road
Xiang'an Torch Industrial Zone
361101 Xiamen
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

Silicone/SEBS/PVC Manual Resuscitators (Including Mask, Positive End-Expiratory Pressure Valve, Oxygen Tube, Reservoir Bag, Mouth opener, Oropharyngeal Airway, Manometer), Resuscitation Mask, Continuous Positive Airway Pressure Mask/Non-invasive Ventilation Mask, Simple Oxygen Mask, Venturi Mask, Non-Rebreathing Mask, Aerosol Mask w/Nebulizer, Breathing Circuit (Including Mask, Elbow Connector, Y Piece, Corrugate Tubing, Collapsible Tubing, Water Trap, Straight Connector, HMEF), Anesthesia Circuit (Including Mask, Elbow Connector w/Luer Port & Cap, Y Piece, Corrugate Tubing, Collapsible Tubing, Straight Connector, Breathing Bag, Bacterial Filter, Gas Sampling Line), Anesthesia Mask, Breathing Filter for Single Use

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G2 063744 0018 Rev. 02

Report No.:	SH20176EXT01
Valid from:	2020-11-04
Valid until:	2024-05-26

Date, 2020-11-04

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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