

Declaration of Conformity

Name of the Device Group(s)	Resuscitation Mask
Model	CP641011
Ref. No./Catalogue No.	ERM0101001
EMDN Code	R030101 VENTILATION MASKS
MDN/MDA code	MDN 1201 Non-active non-implantable devices for anaesthesia, emergency and intensive care
GMDN code	12447
Intended purpose	The Resuscitation Mask with Oxygen Port is designed to assist in providing immediate life support (mouth to mask ventilation) to health emergency victims requiring cardio-pulmonary resuscitation (CPR) rescue techniques.
Classification	Class IIa
Rule:	MDR (EU) 2017/745, Annex VIII, CHAPTER III, Clause 4.2, Rule 2, Paragraph 1, Indent 1
Basic UDI – DI:	694643041244713NN
UDI-DI:	06946430412898
Lot number	Pending
Notified Body:	TÜV Rheinland LGA Products GmbH
Notified Body Address:	Tillystraße 2, 90431 Nürnberg, Germany
Notified Body Identification number:	0197
Manufacturer	Xiamen Compower Medical Tech. Co., Ltd.
Address of manufacturer	Unit 301, No.16, Xianghong Road, Xiang'an Torch Industrial Zone, 361101 Xiamen, P.R. China
SRN of manufacturer	CN-MF-000011703
European Representative	Shanghai International Holding Corp. GmbH (Europe)
Address of European Representative	Eiffestrasse 80, 20537 Hamburg Germany
SRN of authorised representative	DE-AR-000000001
Conformity Assessment Route	MDR (EU) 2017/745, Annex IX, Chapter I and II

We herewith declare that Resuscitation Mask meet the transposition into MDR (EU) 2017/745 and related harmonized Standards. All supporting documentations are retained under the premises of the manufacturer. We are exclusively responsible for the declaration of conformity.

General Medical Device Regulation: MDR(EU)2017/745

Identification number: CE0197

(EC) Certificate(s): HZ 2375149-1

Expire date of the Certificate: 2028-10-12

Start of CE Marking: Pending

Place, Date of Issue: XIAMEN, 2024-05-16

Signature: _____

Name: Bruce Yang

Position: Person responsible for regulatory compliance


 厦门康勃医疗科技有限公司
 XiamenCompowerMedicalTech.Co., Ltd.