

# EU Certificate

Quality Management System  
REGULATION (EU) 2017/745 on Medical Devices, Annex IX Chapter I,  
Section 2 and 3 and Chapter III



Registration No.: HZ 2375149-1

Manufacturer: **Xiamen Compower Medical Tech. Co., Ltd.**  
Unit 301, No.16, Xianghong Road,  
Xiang'an Torch Industrial Zone,  
361101 Xiamen  
P.R. China

EUDAMED Single  
Registration No.: CN-MF-000011703

Products: Products of class IIa:  
R030101 - VENTILATION MASKS  
R030102 - AIR/OXYGEN MASKS AND NASAL CANNULAS  
R030201 - VENTILATION BALLOONS  
R030202 - MANUALLY OPERATED VENTILATION BALLOONS

Authorised  
representative(s): Shanghai International Holding Corp. GmbH (Europe)  
Eiffestrasse 80, 20537 Hamburg, Germany

Certificate history		
Revision:	Description:	Issue date:
0	Initial Revision	2023-10-13

The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled. If class III devices or class IIb implantable devices referred to in the second subparagraph of Article 52(4) are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.9 is required before placing them on the market.

Report No.: 10920784-120  
Effective date: 2023-10-13  
Expiry date: 2028-10-12  
Issue date: 2023-10-13



Wenxiang Zhang  
TÜV Rheinland LGA Products GmbH  
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.

TÜV Rheinland LGA Products GmbH • 51105 Köln

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Date October 13, 2023

**Application for: QMS**

Certificate No. : HZ 2375149-1

Requirement : REGULATION (EU) 2017/745 on Medical Devices, Annex IX  
Chapter I, Section 2 and 3 and Chapter III

Dear Madame or Sir,

Your Quality Management System has been audited and fulfills the above-mentioned requirement.

Enclosed please find the certificate No. HZ 2375149-1.

Best regards,

Wenxiang Zhang  
Certification body



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