By Royal Charter

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 743578 R000

Manufacturer: Ambulanc (Shenzhen) Tech. Co., Ltd.

Address:
3rd and 8th Floor, Block C, Building #5,
and 1st to 10th Floor,
Building #8
Skyworth Innovation
Industry Park
Tangtou 1st Road, Shiyan
Baoan District, Shenzhen
Guangdong
518108
China

Single Registration Number: CN-MF-000010435

EU Authorised Representative: Shanghai International Holding Corp. GmbH (Europe)

Address:
Eiffestraße 80
D-20537 Hamburg
Germany

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2024-09-03**

Current Issue Date: **2024-09-03**

Starting Validity Date: **2024-09-03**

Expiry Date: **2029-09-02**

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Device Schedule: Class III and Class IIb devices

Class III	Intended purpose
Defibrillator/Monitor	See MDR 773839

Class IIb under Rule 12 – Administer and/or remove a medicinal substance	Intended purpose
Ventilator	This product is intended to provide ventilation assistance and breathing support for adult, paediatric and infant patients. The ventilator is intended to be used in intensive care situations within a professional healthcare facility and also suitable for all types of ambulances for emergency transport of the patient.

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	3374546	Issued

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
A Member of the BSI Group of Companies.