

Ambulanc (Shenzhen) Tech. Co., Ltd.

Declaration of Conformity

Product: Transport Ventilator

Model: 6000S

Revision: V2.4

Date: 2024.08.24

DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES

MANUFACTURER: AMBULANC (SHENZHEN) TECH. Co., LTD.
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

MEDICAL DEVICE: Product: Transport Ventilator
Model: 6000S
UMDNS: 18098
GMDN: 36289

CLASSIFICATION - *ANNEX IX*: Class IIb, Rule 11

CONFORMITY ASSESSMENT ROUTE: Annex II, Item 3 (excluding Annex II.4)

WE, AMBULANC (SHENZHEN) TECH. Co., LTD., HEREWITH DECLARE THAT THE STATED
MEDICAL DEVICES MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL
DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES AS AMENDED BY
2007/47/EC AND MDR ARTICLE 120 (3). The manufacturer is exclusively responsible for the
DoC. All supporting documentations are remained under the premises of the manufacturer.

NOTIFIED BODY: SGS BELGIUM NV
Noorderlaan 87, BE-2030 Antwerpen, Belgium

IDENTIFICATION NUMBER 

EC CERTIFICATE: G1 054954 0012 Rev.03

EUROPEAN REPRESENTATIVE: Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, Germany

START OF CE-MARKING: MAR.19,2020

PLACE, DATE OF DECLARATION: SHENZHEN, 2024.08.24

SIGNATURE: 
NAME: WANG CHAOBIN
POSITION: PRRC