

**Ambulanc (Shenzhen) Tech. Co., Ltd.**

**Declaration of Conformity**

Product: Automatic external defibrillator

Model: i7,i9,i7 Plus, i9 Plus

Revision: V1.4

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: Semi-automatic external defibrillator  
Model: i7/i9  
UMDNS: 37805  
GMDN: 47910

CLASSIFICATION - *ANNEX IX*: Class IIb, Rule 9

*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: BSI GROUP THE NETHERLANDS B.V  
SAY BUILDING JOHN M. KEYNESPLEIN 9,1066 EP AMSTERDAM,  
THE NETHERLANDS.

*IDENTIFICATION NUMBER* 

EC CERTIFICATE: 705577

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

START OF CE-MARKING: 2020.09.03

PLACE, DATE OF DECLARATION: SHENZHEN, 2024.08.24

SIGNATURE:

  
NAME: WANG CHAOBIN  
POSITION: PRRC