

Ambulanc (Shenzhen) Tech. Co., Ltd.

Declaration of Conformity

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| Product: | Cardio Pump |
| Model: | 1500 |
| Revision: | V3.0 |
| Date: | October.12, 2020 |

**DECLARATION OF CONFORMITY
TO COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993
CONCERNING MEDICAL DEVICES**

MANUFACTURER: AMBULANC (SHENZHEN) TECH. Co., LTD.
3rd Floor, Block C, Building #5, Skyworth Innovation Industry Park,
Tang Tou 1st Road, Shiyan, Baoan District 518108 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

MEDICAL DEVICE: Product: Cardio Pump
Model: 1500
UMDNS: 13361

CLASSIFICATION - ANNEX IX: Class I, Rule 1

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.

STANDARDS APPLIED: SEE ATTACHED LIST OF (HARMONISED - EN) STANDARDS FOR WHICH
DOCUMENTED EVIDENCE OF COMPLIANCE CAN BE PROVIDED. EN ISO 14971:2012;EN ISO 15223-1:2016;EN
1041:2008;EN ISO 10993-1:2009/AC:2010;EN ISO 10993-5:2009;EN ISO 10993-10:2010;EN 62366:2008;

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

START OF CE-MARKING: MAY 16, 2014

PLACE, DATE OF DECLARATION: SHENZHEN, OCT. 12, 2020

SIGNATURE: 
NAME: RONG LIANG
POSITION: MANAGEMENT REPRESENTATIVE