DECLARATION OF CONFORMITY

According to Regulation (EU) 2017/745

Manufacturer	
Name	Jousing Medical Co., Ltd
SRN:	CN-MF-000008915
Address:	301&401, Building 21, 200 Xingpu Road, Suzhou Industrial Park, Suzhou, Jiangsu 215000, China
Authorised Representative	
Name	Wellkang Ltd
SRN	XI-AR-000001836
Address:	Enterprise Hub, NW Business Complex, 1 Beraghmore Road, Derry, BT48 8SE, Northern Ireland, UK.
Notified Body	
Name	BSI Group The Netherlands B.V.
Address	Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands.
Identification number	2797
Product Information	
Product Name	Automated External Defibrillator
Registered Trade Mark	iAED-S1
Product Model	iAED-S1
EMDN Code	Z12030501
Basic UDI-DI	697331555iAED1QC
MDR Certificate Number	MDR 806583, MDR 806471
Classification and Rule	Class III Rule 1, rule 9, rule 10, rule 11 and rule 22 according to Annex VIII of Regulation (EU) 2017/745.
Conformity Assessment Route	Annex IX according to Regulation (EU) 2017/745
Intended Purpose	iAED-S1 is an automated external defibrillator used to treat victims with suspected cardiac arrest (unresponsive or not breathing normally). After defibrillation electrodes are applied to the victims' chest, iAED-S1 will analyzes the victims' heart rhythm. If a shockable rhythm (either ventricular fibrillation or pulseless ventricular tachycardia) is detected, iAED-S1 will direct the responder to deliver a shock across the heart in order to try

and restore a normal heart rhythm. Use the adult pads for adults over 25 kg to deliver a 150 J shock, and use pediatric pads for pediatric under 25 kg or 0-8 years old to deliver 50 J shock.

The product should be used in public, home, or medical settings by personnel trained in cardiopulmonary resuscitation and automated external defibrillator use, or by medical personnel trained in basic life support and advanced life support courses, or under the guidance of emergency center dispatchers.

Applicable standards

EN ISO 13485:2016/AC:2018
IEC 60601-1:2005+AMD1:2012+AMD2:2020,
IEC 60601-1-2:2014+AMD1:2020,
IEC 60601-2-4:2010+AMD1:2018,
IEC 60601-1-10:2007+AMD1:2013+AMD2:2020,
IEC 60601-1-11:2015+AMD1:2020,
IEC 60601-1-12:2014+AMD1:2020,
IEC 60529:1989+AMD1:1999+AMD2:2013,
IEC 60068-2-53:2010,
ISTA-2A:2011 ISTA Procedure

Declaration Content:

With this Declaration of Conformity, issued under the sole responsibility of Jousing Medical Co., Ltd. as the manufacturer, we hereby declare:

- that the product covered by the present declaration, is in conformity with Regulation(EU) 2017/745;
- that the procedures of Jousing quality management system according to ISO 13485 have been followed, Certificate of Registration No. MD 789431
- that the products do not contain medicinal substances, elements of animal origin or their derivatives,
- are latex free

Signature Yuxi Wang

QA Manager

久心医疗科技(苏州)有限公司
Yuxi Wang, 2025-11-28
Jousing Medical Co., Ltd.