EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 806583 R000

Manufacturer: Jousing Medical Co., Ltd.

Address:
301&401, Building 21
200 Xingpu Road
Suzhou Industrial Park
Suzhou
Jiangsu
215000
China

Single Registration Number: CN-MF-000008915

EU Authorised Representative: Wellkang Ltd

Address:
Enterprise Hub
NW Business Complex
1 Beraghmore Rd.
Derry
BT48 8SE
Northern Ireland

Scope: See attached **Device Schedule**

On the basis of our assessment of the technical documentation in accordance with Regulation (EU) 2017/745, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III 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: **2025-09-15**

Current Issue Date: **2025-09-15**

Starting Validity Date: **2025-09-15**

Expiry Date: **2030-09-14**

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Device Schedule:

Intended Purpose as per the Instructions for Use:

Device 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, device will analyse the victims' heart rhythm. If a shockable rhythm (either ventricular fibrillation or pulseless ventricular tachycardia) is detected, device 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 25kg to deliver a 150J shock and use paediatric pads for paediatric under 25kg or 0-8 years old to deliver 50J 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 centre dispatchers.

Risk Classification: Class III

Device Name	**Model**	**Type** (Codes as per (EU) 2017/2185)	**Basic UDI-DI**
Automated External Defibrillator	iAED-S1	MDA 0305	697331555iAED1QC

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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	30123038	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.

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