Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 096469 0002 Rev. 01

Manufacturer:

Jousing Medical Co., Ltd.
BLDG B2-303, Biobay, 218 Xinghu Street
Suzhou Industrial Park District
215021 Suzhou
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): Automated External Defibrillator

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G1 096469 0002 Rev. 01

Report No.: SH211023EXT01

Valid from: 2021-03-11
Valid until: 2024-05-26

Date, 2021-03-11

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

We, the manufacturer, herewith declare that the product

Automated External Defibrillator

Model: iAED-S1

Basic UDI-DI: 697331555iAED1QC

Meet the transposition into national law, the provisions of council directive 93/42/EEC of 14 June 1993 concerning medical devices; including, at 21 March 2010, The amendments by council Directive 2007/47/EEC all supporting documentation is retained at the premises of the manufacture.
The medical device has been assigned to class IIb, rule 9 according to MDD, Annex IX. It bears the mark

CE 0123

Meet the Article 120.3c of MDR (as amended by (EU) 2023/607).
And the extension until 31 December 2027 has been completed by the EU competent authority.

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 MÜnchen, Germany

Ceitificate No: G1 096469 0002

Issued date: 2021-03-11

Expiry date: 2027-12-31

Following the procedure relating to the EC Declaration of Conformity set out in Annex IV of the Regulation(EU) 2017/745.

This declaration of conformity is valid in connection with the release document for the respective batch of produced devices.