NIHON KOHDEN
SHANGHAI KOHDEN MEDICAL ELECTRONIC INSTRUMENT CORP.
Add: No. 567 Huancheng Bei Road, Shanghai Comprehensive Industrial Development Zone, Fengxian District, Shanghai, 201401, China

Declaration No.: SKXY-10011B

EU DECLARATION OF CONFORMITY

This is a declaration made in accordance with the requirements of the following relevant Union harmonisation legislation. The manufacturer assures that the device that is covered by the present declaration is in conformity with this Regulation (EU) 2017/745 for Medical Devices and, if applicable, with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity. The declaration of conformity is issued under the sole responsibility of the manufacturer.

CE 2797

Manufacturer's Name: SHANGHAI KOHDEN MEDICAL ELECTRONIC INSTRUMENT CORP.

Address: No. 567 Huancheng Bei Road, Shanghai Comprehensive Industrial Development Zone, Fengxian District, Shanghai, 201401, China

SRN: CN-MF-000013567

European Representative: NIHON KOHDEN EUROPE GmbH

Address: Raiffeisenstrasse 10, 61191 Rosbach, Germany

SRN: DE-AR-000010740

■ **Regulation (EU) 2017/745(MDR)**

Notified Body

Name and No. : BSI Group The Netherlands B.V.; 2797

Certificate No. (Conformity assessment procedure): MDR 748567 (Annex IX Chapter I and III)

■ **Directive 2011/65/EU and 2015/863/EU**

Standard Applied: EN 50581:2012

■ **Directive 2014/53/EU (RED)**

Notified Body

Name and No. : MiCOM Labs Inc., No.2280

EU-Type Examination Certificate No. : SGSA77-EU

Standard Applied:

Health and Safety Article 3.1 (a)	IEC 60601-1:2005 IEC 60601-1:2005/AMD1:2012 IEC 60601-1:2005/AMD2:2020 EN 62311:2020 IEC 60601-2-25:2011
EMC Article 3.1 (b)	IEC 60601-1-2:2014 IEC 60601-1-2/AMD1:2020 EN 60601-1-2:2015 IEC 60601-2-25:2011
Spectrum Article 3.2	EN 300 328 V2.2.2 EN 301 893 V2.1.1
Cybersecurity Article 3.3 (d), (e), (f)	Not applicable

Notified Body performed an EU-type examination in accordance with the requirements of Annex III of RE Directive and issued the EU-type examination certificate (Article 3.1(a),3.1(b),3.2).
The device referenced in this declaration is subject to the provisions of Regulation (EU) 2017/745.
Pursuant to Article 2.1 of Commission Delegated Regulation (EU) 2022/30, the essential requirements

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outlined in Article 3.3(d), (e), and (f) of Directive 2014/53/EU shall not apply to the device.

Device Information:

Product Name	Model Number	Class[1]	Basic UDI-DI	MDR	RoHS	RED
Electrocardiograph	ECG-3250	IIa	697001088ECG-32506Q	√	√	√
Software kit	QS-325E	IIa	697001088QS-325E9Y	√	√	×

Intended purpose: The Shanghai Kohden ECG-3250 electrocardiograph is intended for medical use to process the electrical signals produced by the heart, which are acquired through two or more electrodes, and to display waveforms and/or prepare a record of these electrical signals. This device is a portable ECG acquisition terminal which measures up to 12-lead ECG waveforms. The intended use is only for diagnosis, not for monitoring of vital physiological parameters.
ECG-3250 is intended to be used by qualified medical personnel within a medical facility, such as hospital or clinic and neonates, children and adults can be diagnosed with this electrocardiograph.
The software kit QS-325E is the software for ECG-3250. It is intended for upgrading.

Additional Information:

Authorized Signatory:
Shanghai, China/ 2026.3.16
Place and date of issue

Jiaojing Jin
General Manager
Quality Management Division

[1] *According to Annex VIII of the Regulation (EU) 2017/745 (MDR)*