NIHON KOHDEN
SHANGHAI KOHDEN MEDICAL ELECTRONIC INSTRUMENT CORP.
Add : No. 567 Huancheng Bei Road, Shanghai Comprehensive Industrial Development Zone,
Fengxian District, Shanghai, 201401, China
Tel : 0086-21-57436998 Fax : 0086-21-57436936

Declaration No.: SKXY-10011A

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)**

Classification/Risk Class:	IIa
Conformity assessment procedure:	Annex IX Chapter I and III
Notified Body	
Name and No. :	BSI Group The Netherlands B.V.; 2797
EC Certificate:	MDR 748567

■ **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:	IEC 60601-1:2005 IEC 60601-1:2005/AMD1:2012 IEC 60601-1:2005/AMD2:2020 EN 300 328 V2.2.2 EN 301 893 V2.1.1 EN 301 489-17 V3.2.4 EN 301 489-1 V2.2.3 EN 62311:2020

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Product Name, Model Number and Basic UDI-DI :

Product Name	Model Number	Basic UDI-DI	MDR	RoHS	RED
Electrocardiograph	ECG-3250	697001088ECG-32506Q	√	√	√
Software kit	QS-325E	697001088QS-325E9Y	√	√	×
Accessory kit	YD-321D	697001088YD-321D7P	√	√	×
Accessory kit	YD-322D	697001088YD-322D7S	√	√	×
Accessory kit	YD-323D	697001088YD-323D7V	√	√	×
Accessory kit	YD-324D	697001088YD-324D7Y	√	√	×

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/ 2023/6/1
Place and date of issue

Jiaoying Jin
General Manager
Quality Management Division