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.: SKREXY-00004

EU/RE DIRECTIVE DECLARATION OF CONFORMITY

This is a declaration made in accordance with the requirements of Directive 2014/53/EU Of the European Parliament and of the Council of 16 April 2014 on the harmonization of the laws of the Member States relating to the making available on the market of radio equipment. The declaration of conformity is issued under the sole responsibility of the manufacturer.

CE

Manufacturer's Name:	SHANGHAI KOHDEN MEDICAL ELECTRONIC INSTRUMENT CORP.
Business Address:	No.567 Huancheng Bei Road, Shanghai Comprehensive Industrial Development Zone, Fengxian District, Shanghai 201401, China
European Representative:	NIHON KOHDEN EUROPE GmbH
Address:	Raiffeisenstrasse 10, D - 61191 Rosbach, Germany
Product Name and Model Name:	ELECTROCARDIOGRAPH ECG-3350
Notified Body's Name and No.:	UL Japan, Inc., No.1731(Module B)
EU-Type examination Certificate No.:	ULAR2003038

Standard Applied:

IEC 60601-1: 2005
IEC 60601-1 Amendment 1: 2012
IEC 60601-1-2: 2014
EN 60601-1-2: 2015
IEC 60601-2-25: 2011
EN 60601-2-25:1995+A1:1999
IEC 60601-2-25:1993+A1:1999
EN 300 328 V2.1.1
EN 301 893 V2.1.1
EN 62311: 2008

Authorized Signatory:

Shanghai, China / 2020.5.19
Place and date of issue

Jiaoying Liu
Jiaoying Liu
General Manager
Quality Management Division

様式 RE4

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-00010

EC/MDD DECLARATION OF CONFORMITY

This is a declaration made in accordance with the requirements of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC).

CE 2797

Manufacturer's Name:	SHANGHAI KOHDEN MEDICAL ELECTRONIC INSTRUMENT CORP.
Business Address:	No. 567 Huancheng Bei Road, Shanghai Comprehensive Industrial Development Zone, Fengxian District, Shanghai, 201401, China
European Representative:	NIHON KOHDEN EUROPE GmbH
Address:	Raiffeisenstrasse 10, D - 61191 Rosbach, Germany
Product Name and Model Name:	Electrocardiograph ECG-3350 Software kit QS-335E
Classification:	IIa

Each kind of medical device to which the Full Quality Assurance Procedures (Annex II excluding Section 4) have been applied complies with the applicable provisions of the essential requirements, the classification rules, at each stage, from the design of the device until its final inspection before being supplied.

Notified Body:	BSI Group The Netherlands B.V. Address: Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, Netherlands Tel: + 31 20 346 0780 Number: 2797
EC Certificate:	CE 585273
Standard Applied:	EN ISO 14971:2012; ISO 14971:2012 EN ISO 13485:2016; ISO 13485:2016 EN 60601-1:2006+A1:2013; IEC 60601-1:2012 reprint IEC 60601-2-25:2011 EN 60601-1-2:2015; IEC 60601-1-2:2014 ISO 10993-5:2009 ISO 10993-10:2010 ISO 10993-12:2012 EN 60601-1-6:2010+A1:2015; IEC 60601-1-6:2010+A1:2013 EN 62366:2008+A1:2015; IEC 62366:2007+A1:2014 IEC 62133:2002 EN 62304:2006+A1:2015; IEC 62304:2006+A1:2015 EN 1041:2008+A1:2013 EN ISO 15223-1:2016

Authorized Signatory:

Shanghai, China / 2020.5.19
Place and date of issue

Jiaoying Liu
General Manager
Quality Management Division

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.: SK/RXY-00009

RoHS DECLARATION OF CONFORMITY

This is a declaration made in accordance with the requirements of Council Directive 2011/65/EU of 8 June 2011 and 2015/863/EU of 31 March 2015 concerning the restriction of the use of certain hazardous substances in electrical and electronic equipment.

CE

Manufacturer's Name: SHANGHAI KOHDEN MEDICAL ELECTRONIC INSTRUMENT CORP.
Business Address: No. 567 Huancheng Bei Road, Shanghai Comprehensive Industrial Development Zone, Fengxian District, Shanghai, 201401, China

We hereby certify that following product(s) conform to the European Union's Restriction on Use of Hazardous Substances in Electrical and Electronic equipment (RoHS) Directive 2015/863/EU for ten regulated substances listed below.

Product Name(s):

ELECTROCARDIOGRAPH	ECG-3350
ACCESSORY KIT	YD-321D
ACCESSORY KIT	YD-322D
ACCESSORY KIT	YD-323D*
ACCESSORY KIT	YD-324D
BATTERY PACK	NKB-301V

（*YD-323D conforms to 1）～6）before JUN 2021 ）

List of environmentally hazardous substances:

1) Lead
2) Mercury
3) Cadmium
4) Hexavalent Chromium
5) Polybrominated biphenyls (PBB)
6) Polybrominated diphenyl ethers (PBDE)
7) Bis(2-ethylhexyl) phthalate (DEHP)
8) Butyl benzyl phthalate (BBP)
9) Dibutyl phthalate (DBP)
10) Diisobutyl phthalate (DIBP)

Harmonized Standards Applied:

Authorized Signatory:

Shanghai, China / 2020. 5. 25
Place and date of issue

Jiaoying Jin
General Manager
Quality Management Division