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-00002

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-3150
Notified Body's Name and No.:	UL Japan, Inc., No.1731(Module B)
EU-Type examination Certificate No.:	ULAR1904057
Standard Applied:	IEC 60601-1: 2005 IEC 60601-1 Amendment 1: 2012 IEC 60601-2-25: 2011 IEC 60601-1-2: 2014 EN 300 328 V2.1.1 EN 301 893 V2.1.1 EN 62311: 2008

Authorized Signatory:

Shanghai, China / 2019.5.31
Place and date of issue

Jiaoying Liu
Jiaoying Liu
General Manager
Quality Management Division

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NIHON KOHDEN
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Declaration No.: SKXY-00008

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-3150
Classification:	IIa

The cardiofax C ECG-3150 has a rechargeable battery pack, multiple recording methods, LCD electrocardiogram waveform display. It meets the demands of hospitals, scientific research, general wards, rescue and visiting a patient at home.

Notified Body:	BSI Group The Netherlands B.V. Address: Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, Netherlands Tel: + 31 20 346 07801773 Number: 2797
EC Certificate:	CE 585273
Standard Applied:	EN ISO 14971:2012; ISO 14971:2012 EN ISO 13485:2016 EN ISO 15223-1:2012 EN 60601-1:2006/A1:2013; IEC 60601-1:2012 EN 60601-1-2:2007+AC:2010; IEC 60601-1-2:2014 EN 62366:2008; IEC 62366:2007 EN 62304:2006; IEC 62304:2006 EN 1041: 2008+A1:2013 ISO 10993-5:2009 ISO 10993-10:2010 ISO 10993-12:2012 EN 60601-1-6:2010; IEC 60601-1-6:2010 IEC 60601-2-25:2011 IEC 62133: 2017

Authorized Signatory:

Shanghai, China / 2019.4.30
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-00008

RoHS DECLARATION OF CONFORMITY

This is a declaration made in accordance with the requirements of Council Directive 2011/65/EU of 8 June 2011 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 2011/65/EU for six regulated substances listed below.

Product Name and Model Name:	Electrocardiograph	ECG-3150
Accessories name and Model Name:	Battery Pack	SB-301DC
	Accessory kit	YD-311D
	Accessory kit	YD-312D
	Accessory kit	YD-313D
	Accessory kit	YD-314D

List of environmentally hazardous substances:

1) Lead
2) Mercury
3) Cadmium
4) Hexavalent Chromium
5) Polybrominated biphenyls (PBB)
6) Polybrominated diphenyl ethers (PBDE)

Harmonized Standards Applied: EN50581:2012

Authorized Signatory:
Shanghai, China / 2019.5.30
Place and date of issue

Jiaoying Liu
General Manager
Quality Management Division