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-10009B

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. : SGS FIMKO OY, No.0598

EU-Type Examination Certificate No. : HEL-CERT190300135-01 Issue no.2 (SVM-7130, SVM-7160)
HEL-CERT190300134-01 Issue no.2 (QI-710P)

Standard Applied:

Health and Safety Article 3.1 (a)	EN 60601-1:2006+A2:2021 (SVM-7130, SVM-7160) EN IEC 62311:2020
EMC Article 3.1 (b)	EN 60601-1-2:2015+A1:2021 (SVM-7130, SVM-7160) EN 301 489-1 V2.2.3 EN 301 489-17 V3.2.4
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 outlined in Article 3.3(d), (e), and (f) of Directive 2014/53/EU shall not apply to the device.

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Device Information:

Product Name	Model Number	Class[1]	Basic UDI-DI	MDR	RoHS	RED
Vital Signs Monitor	SVM-7130	IIb	697001088SVM-7130U4	√	√	√
Vital Signs Monitor	SVM-7160	IIb	697001088SVM-7160UD	√	√	√
Software Kit	QS-117P	IIb	697001088QS-117PA9	√	√	×
Interface	QI-716P	IIa	697001088QI-716P7E	√	√	×
Interface	QI-717P	IIa	697001088QI-717P7H	√	√	×
Temperature Module	AW-711P	IIa	697001088AW-711P45	√	√	×
Recorder Module	WS-710P	IIa	697001088WS-710PE4	√	√	×
Wireless LAN Module	QI-710P	IIa	697001088QI-710P6U	√	√	√

Intended purpose:

①The SVM-7130 and SVM-7160 monitors can be used as vital signs monitors, and are intended to be used by clinicians, doctors, nurses and medically qualified personnel for measuring non-invasive blood pressure (NIBP), non-invasive functional oxygen saturation of arteriolar hemoglobin (SpO_2), body temperature (TEMP) of one patient at a time, and can be used for several patients and generate alarms.

②The QS-117P is the software upgrade package for qualified service personnel to update the software version of SVM-7130 and SVM-7160 vital signs monitor.

③The QI-716P interface is for the SVM-7100 series vital signs monitor. The interface can display temperature value that is measured by Exergen's infrared thermometer TAT-5000S-RS232-QR.

④The QI-717P interface is an interface which connects SVM-7100 series vital signs monitor and RADIANT's infrared ear thermometer THP59JU.

⑤The AW-711P temperature module is for the SVM-7100 series vital signs monitor. The temperature module can measure oral, axillary or rectal temperature.

⑥The WS-710P recorder module is for the SVM-7100 series vital signs monitor. The recorder module can record the waveform data of the patients' vital signs and print this data through communication with the monitor.

⑦The QI-710P wireless LAN module is for the SVM-7100 series vital signs monitor. By the WLAN module, the vital signs monitor can conduct the patients' vital signs communication with central monitor or other monitors.

Additional Information:

Authorized Signatory:

Shanghai, China/ 2025.9.10
Place and date of issue

Jiaoying Jin
General Manager
Quality Management Division

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