Xuzhou Kaixin Electronic Instrument Co., Ltd.
Kaixin Mansion, C-01, Economic Development Zone, Xuzhou, Jiangsu, China.
Tel: +86-516-87732932 87733758

Declaration of Conformity

Manufacturer: Xuzhou Kaixin Electronic Instrument Co., Ltd.
Address: Kaixin Mansion, C-01, Economic Development Zone, Xuzhou, Jiangsu, China.
Zip Code: 221004
European Representative: Shanghai International Holding Corp. GmbH (Europe)
Address: Eiffestrasse 80, 20537 Hamburg, Germany
Tel.: 0049-40-2513175
Fax: 0049-40-255726

Product Name: Ultrasonic Diagnostic Instruments (Ophthalmological A/B mode ultrasound scanner)
Model Number: ODU3, ODU5
UMDNS Code: 14278
Classification(MDD,Annex IX): IIa (Rule10)
Conformity Assessment Route: EC Directive 93/42/EEC Annex II excluding (4)

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directive and Standards. All supporting documentations are retained under the premises of the manufacturer. We are exclusively responsible for the Declaration of Conformity.
Standard applied:

IEC 60601-1:2005+ A1:2012	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2:2014	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests
IEC 60601-2-37:2007/ AMD1:2015	Medical electrical equipment: – Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
2011/65/EU(RoHS)	DIRECTIVE 2011/65/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment
EN 62321:2009	Electrotechnical Products - Determination of Levels of six Regulated Substances (lead, Mercury, Cadmium, Hexavalent Chromium, Polybrominated Biphenyls, Polybrominated Diphenyl Ethers)

EN ISO 14971: 2012	Medical devices – Application of risk management to medical devices
IEC 62304:2006/AMD1:2015	Medical device software – software life-cycle processes
IEC 62366-1:2015	Medical device – Part 1: Application of usability engineering to medical devices
EN ISO 15223-1: 2012	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
EN 1041/A1:2013	Information supplied by the manufacturer of medical devices
ISO 10993-1: 2018	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
ISO 10993-5: 2009	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
ISO 10993-10: 2010	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization

DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical device, amended by Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 (MDD93/42/EEC).

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstraße 65 80339 MÜNCHEN Germany

Identification number: 0123

(EC) Certificate(s): G1 052731 0032 Rev. 00

Expire date of the Certificate: 2024-05-26

Start of CE Marking: 2012-01-10

Date of issue: 2020-04-01

Signature:

Name: Guozheng Bu

Position: General Manager

Digitally signed by Botnaru Andrei
Date: 2022.10.17 11:02:11 EEST
Reason: MoldSign Signature
Location: Moldova