EU Declaration of Conformity
Regarding Medical Device Regulation(EU)2017/745

Manufacturer

Company: Beijing Konted Medical Technology Co., Ltd,

Address: Room 111, Building 3, No. 27 , Yongwang Road, Daxing Biological Pharmaceutical Industry Base, Daxing District,102629 Beijing, PEOPLE' S REPUBLIC OF CHINA

SRN: CN-MF-000024104

European Representative

Company: SUNGO Cert GmbH
Address: Harffstr. 47,40591 Düsseldorf, Germany
E-mail: de.rep@sungogroup.com
SRN: DE-AR-000010869

Product

Name: Pocket Ultrasound System

Intended use

The Pocket Ultrasound System is designed used for diagnostic ultrasound imaging and fluid flow analysis of the human body for general clinical applications.

Indications

Obstetrics、Gynaecology、Abdominal Small Parts (breast, thyroid, testicle, etc)、Cardiology、Peripheral Vascular、Muscular-Skeletal、Nerve、Urology、Orthopedic、Angiography、Physical Examinations、Digestion、Paediatrics、Paracentesis.

The Pocket Ultrasound System C10 is designed with four ultrasound modes of operation, including B-mode, Combination Mode (B+M mode), Color Doppler mode and Pulsed Wave Doppler mode.

Intended user

The system is only intended for use by qualified healthcare practitioners (e.g., doctors, nurses, sonographers) who are trained in the use of ultrasound imaging technology.

EMDN code: Z11040104

Product Name	Basic UDI-DI
Pocket Ultrasound System	697387564C10SU

Models: C10
Classification: Class IIa
Rules: Rule 10, Annex VIII and MDCG 2021-24, Medical Device Regulation (EU)2017/745
Conformity assessment procedure: Chapter I+III, Sec.4 of Annex IX
Notified Body: SGS Belgium NV

Address:Noorderlaan 87

BE-2030 Antwerpen

Belgium

Notified Body number 1639

EC certificate no: CN24/00006331

Issue date: 09 October 2024

Valid until: 09 October 2029

Manufacturer of the above products, hereby declare under our sole responsibility for this Declaration of Conformity that the referenced products comply with all relevant provisions of MDR Regulation(EU)2017/745 and RED EN 300328:2017, and its transposition into national laws. The products comply with the General Safety and Performance Requirements of Annex I,

further applicable standards/common specifications and/or other normative documents as listed in the applicable technical documentation. All supporting documentation is kept under the premises of the manufacturer

The above referenced products will bear the CE mark as below.

CE 1639

We confirm our product meets the requirements of Medical Device Regulation (EU)2017/745 and the following harmonized standards/common specifications.

No.	Standard No.	Version	Title
1	Regulation(EU) 2017/745	2017	Medical Device Regulation
2	RED EN 300328	2017	Wideband transmission systems;Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques; Harmonised Standard for access to radio spectrum
3	EN ISO 14971	2019/A11:2021	Medical Device -Application of Risk Management in Medical Device
4	EN ISO 15223-1	2021	Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied General requirements.
5	EN ISO 20417	2021	Medical devices - Information to be supplied by the manufacturer
6	EN ISO 10993-1	2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
7	EN ISO 10993-5	2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)
8	ISO 10993-10	2021	Biological evaluation of medical devices-Part 10: Tests for skin sensitization
9	EN ISO 10993- 23	2021	Biological evaluation of medical devices - Part 23 Tests for irritation
10	EN ISO13485	2016	Quality system-Medical devices-Particular requirements
11	EN 60601-1	2006 + A12: 2014	Medical electrical equipment - 1: General requirements for basic safety and essential performance
12	EN 60601-1-2	2015	Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests
13	EN 60601-1-11	2015	Medical electrical equipment. General requirements for basic safety and essential performance. Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
14	EN 60601-2-37	2008+A1:2015	Medical electrical equipment — Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
15	EN 60601-1-6	2010	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability (IEC 60601-1-6:2010)
16	EN 62366	2015	Medical devices - Application of usability engineering to medical devices

17	EN 62304	2006+A1:2015	Medical device software-Software life cycle processes
18	EN 62368-1	2014+A11:2017	Audio/video, information and communication technology equipment - Part 1: Safety requirements
19	EN 62479	2010	Assessment of the compliance of low power electronic and electrical equipment with the basic restrictions related to human exposure to electromagnetic
20	EN 301489-1-17	2019	Electromagnetic compatibility and Radio spectrum Matters(ERM); ElectroMagnetic Compatibility(EMC) standard for radio equipment;Part 17:Specific conditions for Broadband Data Transmission Systems
21	EN 300440	2017	Short Range Devices (SRD) - Radio equipment to be used in the 1 GHz to 40 GHz frequency range - Harmonised Standard covering the essential requirements of article 3.2 of the Directive 2014/53/EU (Endorsement of the English version
22	EN 301893	2017	Broadband Radio Access Networks (bran) - 5 Ghz High Performance Rlan - Harmonized En Covering The Essential Requirements Of Article 3.2 Of The R&tte Directive
23	(RED) 2014/53/EU	2014	Radio Equipment Directive
24	ASTM-D4169-22		Standard Practice for Performance Testing of Shipping Containers and Systems
25	ASTM-D642-15		Test Method for Determining Compressive Resistance of Shipping Container, Components, and Unit Loads.
26	ASTM-D5276-98		Test Method for Drop Test of Loaded Container by Free Fall
27	ASTM-D5487-98		Test Method for Shock Test of Packaged Product.
28	ISO2859-1	2011	Sampling procedures for inspection by attributes — Part 1:Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection
29	ISO/TR 20416	2020	Medical devices - Post-market surveillance for manufacturers
30	MDCG 2021-24		Guidance on classification of medical devices
31	MDCG 2020-7		Post-market clinical follow-up (PMCF) Plan Template A guide for manufacturers and notified bodies
32	MDCG 2020-8		Post-market clinical follow-up (PMCF) Evaluation Report Template A guide for manufacturers and notified bodies
33	MDCG 2020-5		Clinical Evaluation - Equivalence A guide for manufacturers and notified bodies
34	MDCG 2020-6		Regulation (EU) 2017/745: Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC A guide for manufacturers and notified bodies
35	MEDDEV 2.7.1 rev.4	2016	CLINICAL EVALUATION: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES
36	MEDDEV 2.12-1 rev.8		GUIDELINES ON A MEDICAL DEVICES VIGILANCE SYSTEM
37	MEDDEV 2.12-2 rev.2		GUIDELINES ON POST MARKET CLINICAL FOLLOW-UP
38	EN60601-12	2014+A1：2020	General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment

Name and Signature: Deyi Zhu
Date and Place: 2024.10.9 Beijing

Position: PRRC