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

Manufacturer

Company: Guangzhou Sonostar Technologies Co., Ltd.
Address:504#, C Building, #27 Yayingshi Road, Science Town, 510655 Guangzhou, PEOPLE'S REPUBLIC OF CHINA
SRN: CN-MF-000030303

European Representative

Company: SUNGO Europe B.V.
Address: Fascinatio Boulevard 522, Unit 1.7, 2909VA Capelle aan den IJssel, The Netherlands
SRN: NL-AR-000000247

Product

Name: Wireless Probe Type Ultrasound Scanner
EMDN code: Z110401 MDA:0203

Product Name	Basic UDI-DI
Wireless Probe Type Ultrasound Scanner	697067275WirelessProbeR7

Models: UProbe-L、UProbe-C、BProbe、CProbe-C、CProbe-L、CProbe-CL、CProbe-CT
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

Intertek Medical Notified Body AB
Torshamnsgatan 43, Box 1103
SE-164 22 Kista, Sweden
Notified Body number: CE_{2862}
EC certificate No.: 28620203593
Issue date: 2025.1.22
Valid until: 2029.11.18

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 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 2862

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
Harmonized Standards			
1.	EN ISO 13485	2016+AC:2018+ A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes
2.	EN ISO 10993-10	2023	Biological Evaluation of Medical Device - Part 10: Tests for skin sensitization
3.	ISO 10993-23	2021	Biological evaluation of medical devices - Part 23: Tests for irritation
4.	EN ISO 14971	2019+A11:2021	Medical devices - Application of risk management to medical devices
Other Applicable standards			
5.	Regulation(EU) 2017/745	2017	Medical Device Regulation
6.	EN ISO 15223-1	2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
7.	EN ISO 20417	2021	Medical devices - Information to be supplied by the manufacturer
8.	EN ISO 10993-1	2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
9.	EN ISO 10993-5	2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
10.	EN 60601-1	2006+A2:2021	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
11.	EN 60601-1-2	2015+A1:2021	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances. Requirements and tests
12.	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
13.	EN 60601-1-6	2010	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
14.	EN 62366	2015+A1:2020	Medical devices - Application of usability engineering to medical devices
15.	EN 62304	2006+A1:2015	Medical device software-Software life-cycle processes
16.	EN ISO 14155	2020	Clinical investigation of medical devices for human subjects - Good clinical practice
17.	EN 60950-1	2006+A2:2013	Information technology equipment-Safety-Part 1: General requirements

18.	EN 62479	2010	Assessment of the compliance of low-power electronic and electrical equipment with the basic restrictions related to human exposure to electromagnetic fields (10 MHz to 300 GHz)
19.	ETSI EN 301 489-1	2019	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonised Standard for ElectroMagnetic Compatibility
20.	ETSI EN 301 489-17	2020	ElectroMagnetic compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for Broadband Data Transmission Systems; Harmonised Standard for ElectroMagnetic Compatibility
21.	ETSI EN 300 328	2019	Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz band; Harmonised Standard for access to radio spectrum
22.	(RED)2014/53/EU	2014	Radio Equipment Directive
23.	ASTM-D4169	2023	Standard Practice for Performance Testing of Shipping Containers and Systems
24.	ISO2859-1	2011	Sampling procedures for inspection by attributes - Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection
25.	ISO/TR 20416	2020	Medical devices - Post-market surveillance for manufacturers

Reference Guidance

Item.	Guidance	Title
1.	MEDDEV 2.4/1 rev.9 (2010)	MEDICAL DEVICES: Guidance document - Classification of medical devices
2.	MEDDEV 2.7.1 rev.4 (2016)	CLINICAL EVALUATION: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES UNDER DIRECTIVES 93/42/EEC and 90/385/EEC
3.	MEDDEV 2.12-1 rev.8	GUIDELINES ON A MEDICAL DEVICES VIGILANCE SYSTEM
4.	MEDDEV 2.12-2 rev.2	GUIDELINES ON POST MARKET CLINICAL FOLLOW-UP STUDIES
5.	MDCG 2020-5	Clinical Evaluation - Equivalence A guide for manufacturers and notified bodies
6.	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
7.	MDCG 2020-7	Post-market clinical follow-up (PMCF) Plan Template A guide for manufacturers and notified bodies
8.	MDCG 2020-8	Post-market clinical follow-up (PMCF) Evaluation Report Template A guide for manufacturers and notified bodies
9.	MDCG 2021-24	Guidance on classification of medical devices
10.	GHTF SG5/N2R8	Clinical Evaluation

Name and Signature: Xu Peida Position: PRRC

Date and Place: 18 Mar. 2025, Guangzhou