Qisda Corporation

Headquarters & Taoyuan Business Center
157 Shanying Road, Gueishan
Taoyuan 333, Taiwan, R. O. C.
Tel : +886-3-359-5000
Fax : +886-3-359-9000

Declaration of Conformity

Manufacturer information as

Name: **Qisda Corporation**

Address: **NO. 157, SHAN-YING ROAD, SHAN-TING LI, GUEISHAN DIST., TAOYUAN CITY, TAIWAN, R.O.C.**

SRN: **TW-MF-000010709**

Declare under our sole responsibility that the product,

Product	Diagnostic Ultrasound System
Basic UDI-DI	471987300VIVAPRO5J

Product identification	Model name	Reference number
InnoSight Diagnostic Ultrasound System	InnoSight	989605460371
"BenQ" Diagnostic Ultrasound System	T3300	T3300
"Esaote MyLabX1" diagnostic ultrasound system		
"BenQ" Diagnostic Ultrasound System	H1300	H1300

EMDN code(s): Z11040103 (PORTABLE ULTRASOUND SCANNERS)

Classification: Class IIa in accordance with Annex VIII, Rule 10 of the Medical Device Regulation 2017/745

Classification: Class 2 Radio Equipment according to the RED Directive 2014/53/EU.

Intended use: diagnostic ultrasound imaging and fluid flow analysis of human body

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Options items (Accessories) are listed below based on Annex VIII 3.2 of MDR,

InnoSight:

Option No.	Description	Type	Classification
C1	Cart	Accessory	N/A
M1	MTM	Accessory	N/A
S1	Carry case	Accessory	N/A
T1	Transducer C6-2 (Curve Array)	Accessory	IIa
T2	Transducer L12-4 (Linear Array)	Accessory	IIa
T3	Transducer C9-4v (Curve Array)	Accessory	IIa
T4	Transducer S4-2 (Phase Array)	Accessory	IIa
T5	Transducer C83B (Curve Array)	Accessory	IIa
P1	External Printer	Compatible device	N/A
P2	Medical grade AC/DC power adapter	Accessory	N/A

T3300:

Option No.	Description	Type	Classification
M1	BenQ Multiple Transducer Module	Accessory	N/A
T1	Transducer C62B_T3300 (Curve Array)	Accessory	IIa
T2	Transducer C83B_T3300 (Curve Array)	Accessory	IIa
T3	Transducer E94B_T3300 (Curve Array)	Accessory	IIa
T4	Transducer L154BH_T3300 (Linear Array)	Accessory	IIa
T5	Transducer L187BH_T3300 (Linear Array)	Accessory	IIa
T6	Transducer P42B6_T3300 (Phase Array)	Accessory	IIa
P1	Medical grade AC/DC power adapter	Accessory	N/A

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H1300:

Option No.	Description	Type	Classification
T1	Transducer C62B_H1300 (Curve Array)	Accessory	IIa
T2	Transducer C83B_H1300 (Curve Array)	Accessory	IIa
T3	Transducer E94B_H1300 (Curve Array)	Accessory	IIa
T4	Transducer L154BH_H1300 (Linear Array)	Accessory	IIa
T5	Transducer L187BH_H1300 (Linear Array)	Accessory	IIa
T6	Transducer P42B6_H1300 (Phase Array)	Accessory	IIa
T7	Transducer P83B6_H1300 (Phase Array)	Accessory	IIa
P1	Medical grade AC/DC power adapter	Accessory	N/A

The object of the declaration described above is in conformity with:

- Medical Device Regulation 2017/745 concerning medical devices;
- Directive 2014/53/EU on radio equipment and telecommunications terminal equipment;
- Directive 2014/30/EU relating to electromagnetic compatibility;
- 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.

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Conformity assessment procedure:

Conformity assessment was performed according to ***Annex IX full quality assurance system*** *of the Medical Device Regulation 2017/745 under the supervision of Notified Body Number 1639, SGS Belgium NV, SGS House, Noorderlaan 87 2030 Antwerpen Belgium.*

Certificate number:

The Authorized Representative within the EU who has been empowered to enter into commitments on our behalf is:

MedNet EC-REP GmbH

Borkstrasse 10, 48163 Münster, Germany

SRN:DE-AR-000000002

Note that the Notified Body number does not apply to the RoHS Directive nor the RED.

We confirm that technical documentation has been prepared for each device.

This declaration is issued under the sole responsibility of the manufacturer.

Additional Information:

The products listed above have been tested in a typical configuration as described in the Manufacturer's accompanying documentation, and are fully compliant with the standards listed below. Additionally, the products listed above have been designed, manufactured, tested, and found to be compatible with the devices and accessories described by the manufacturer in the devices accompanying Instructions for Use. The radio transmitting equipment listed above was tested in accordance with Article 10, via Annex III, of the RED, and all essential radio test suites (as defined by the Essential Requirements) have been carried out. This product is intended to connect to the Publicly Available Interfaces (PAI) and used throughout the EEA. Individual Countries may apply restrictions on putting this device into service or placing on the market.

Products described above and labels with the "CE Mark" are in conformance with:

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Standard

Item	Document No.	Item	Document No.
1	EN ISO 13485:2016+A11:2021	11	EN 62366-1:2015+AMD1:2020
2	EN ISO 15223-1:2021	12	EN 60601-1: 2006+A2:2021
3	EN ISO 14971:2019+A11:2021, CEN ISO/TR 24971:2020	13	EN 60601-1-6:2010+AMD1:2015
4	EN ISO 10993-1:2020	14	EN 60601-1-2:2015+A1:2021
5	EN ISO 10993-5:2009	15	EN 60601-2-37:2008 + A1:2015
6	EN ISO 10993-10:2023	16	EN 300 328 V2.2.2:2019
7	EN ISO 10993-18:2020+A1:2023	17	EN 301 893 V2.1.1:2017
8	EN ISO 10993-23:2021	18	EN 301 489-1 V2.2.3:2019-11
9	EN ISO 20417:2021	19	EN 301 489-17 V3.2.4:2020-09
10	EN 62304:2006+A1:2015	20	EN IEC 62311:2020

Common Specification（if applicable）: Not Applicable

Operation frequency and radio-frequency power are listed as below:

WLAN 802.11b/g/n/a 2400-2483.5MHz < 20dBm ; 5150- 5250MHz < 18 dBm

Signed for and on the behalf of Qisda, Taiwan :

2024/10/4

Date: YYYY/MM/DD

Lawrence / Director
Medical Imaging Business Unit
Medical Device BG