

DECLARATION OF CONFORMITY

MANUFACTURER

Name: CANON MEDICAL SYSTEMS CORPORATION

Address: 1385, Shimoishigami, Otawara-Shi, Tochigi 324-8550, JAPAN

AUTHORIZED REPRESENTATIVE

Name: CANON MEDICAL SYSTEMS EUROPE BV

Address: Zilverstraat 1, 2718 RP Zoetermeer, THE NETHERLANDS

ACCESSORY (MDD article 1 section2 (b))

Generic name: Diagnostic Ultrasound Transducers, Sono Coupler
Biopsy adapters and water bags of CUS-X100G
See attached data sheet

We, Canon Medical Systems Corporation, declare that the medical device as specified above is in conformity with the provisions of Directive 93/42/EEC and subsequent amendments and the requirements of 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. An overview of applied harmonized standards is maintained.

Any modification to the medical device not authorized in writing by Canon Medical Systems Corporation will invalidate this declaration.

This declaration except the requirements of Directive 2011/65/EU is supported by EC quality system approval certification registration number HD 60125549 0001 issued by TÜV Rheinland LGA Products GmbH (0197), covering the provisions of Annex II, excluding section 4 of Directive 93/42/EEC and subsequent amendments.

Place: Otawara-Shi Date: 15 May 2019

Signature: _____



Koichi Mikami

Senior Manager

Quality & Environment Assurance Department

Quality, Safety and Regulation Center

CUS-X100G's accessories

No	Description	Model	Classification
1	PHASED ARRAY TRANSDUCER	PSU-25BT	Class IIa
2	PHASED ARRAY TRANSDUCER	PSU-30BT	Class IIa
3	PHASED ARRAY TRANSDUCER	PSU-50BT	Class IIa
4	PHASED ARRAY TRANSDUCER	PSU-70BT	Class IIa
5	CONVEX ARRAY TRANSDUCER	PVU-350BTP	Class IIa
6	CONVEX ARRAY TRANSDUCER	PVU-375BT	Class IIa
7	CONVEX ARRAY TRANSDUCER	PVU-382BT	Class IIa
8	CONVEX ARRAY TRANSDUCER	PVU-674BT	Class IIa
9	CONVEX ARRAY TRANSDUCER	PVU-674MV	Class IIa
10	CONVEX ARRAY TRANSDUCER	PVU-681MVL	Class IIa
11	CONVEX ARRAY TRANSDUCER	PVU-712BT	Class IIa
12	CONVEX ARRAY TRANSDUCER	PVU-745BTF	Class IIa
13	CONVEX ARRAY TRANSDUCER	PVU-745BTH	Class IIa
14	CONVEX ARRAY TRANSDUCER	PVU-745BTV	Class IIa
15	CONVEX ARRAY TRANSDUCER	PVU-770ST	Class IIa
16	CONVEX ARRAY TRANSDUCER	PVU-781VT	Class IIa
17	CONVEX ARRAY TRANSDUCER	PVU-781VTE	Class IIa
18	ENDOCAVITARY TRANSDUCER	PVL-715RS	Class IIa
19	LINEAR ARRAY TRANSDUCER	PLU-308BTP	Class IIa
20	LINEAR ARRAY TRANSDUCER	PLU-704BT	Class IIa
21	LINEAR ARRAY TRANSDUCER	PLU-705BTF	Class IIa
22	LINEAR ARRAY TRANSDUCER	PLU-705BTH	Class IIa
23	LINEAR ARRAY TRANSDUCER	PLU-1005BT	Class IIa
24	LINEAR ARRAY TRANSDUCER	PLU-1202BT	Class IIa
25	LINEAR ARRAY TRANSDUCER	PLU-1204BT	Class IIa
26	MULTIPLANE TRANSESOPHAGEAL TRANSDUCER	PET-512MA	Class IIa
27	MULTIPLANE TRANSESOPHAGEAL TRANSDUCER	PET-512MC	Class IIa
28	MULTIPLANE TRANSESOPHAGEAL TRANSDUCER	PET-512MD	Class IIa
29	LINEAR ARRAY TRANSDUCER	PET-805LA	Class IIa
30	CW DOPPLER PENCIL TRANSDUCER	PC-20M	Class IIa
31	CW DOPPLER PENCIL TRANSDUCER	PC-50M	Class IIa
32	SONO COUPLER	UACK-003A	Class IIa
33	SONO COUPLER	UACK-004A	Class IIa
34	BIOPSY ADAPTER	UAGL-001AHA	Class IIa
35	BIOPSY ADAPTER	UAGL-002AHA	Class IIa

No	Description	Model	Classification
36	BIOPSY ADAPTER	UAGL-004AHA	Class IIa
37	BIOPSY ADAPTER	UAGV020A	Class IIa
38	BIOPSY ADAPTER	UAGV-027A	Class IIa
39	BIOPSY ADAPTER	UAGV-028A	Class IIa
40	BIOPSY ADAPTER	UAGV-029A	Class IIa
41	BIOPSY ADAPTER	UAGV-030A	Class IIa
42	BIOPSY ADAPTER	UAGV-034A	Class IIa
43	BIOPSY ADAPTER	UAGV-035A	Class IIa
44	BIOPSY ADAPTER	UAGV-036A	Class IIa
45	Water Bag	UAWB-021A	Class IIa
46	Water Bag	UAWB-022A	Class IIa

Classification: Refer to the Article 9 of MDD

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