

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 TUS-A300
See attached data sheet

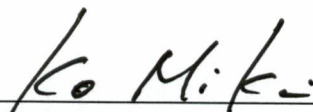
We, Canon Medical Systems Corporation, declare that the medical device as specified above is in conformity with the provisions of Directive 93/42/EEC and subsequent amendments and the requirements of Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction 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: 26 April 2019

Signature: _____



Koichi Mikami

Senior Manager

Quality & Environment Assurance Department

Quality, Safety and Regulation Center

TUS-A300's accessories

No	Description	Model	Classification
1	PHASED ARRAY TRANSDUCER	PST-25BT	Class IIa
2	PHASED ARRAY TRANSDUCER	PST-30BT	Class IIa
3	PHASED ARRAY TRANSDUCER	PST-50BT	Class IIa
4	CONVEX ARRAY TRANSDUCER	PVT-350BTP	Class IIa
5	CONVEX ARRAY TRANSDUCER	PVT-375BT	Class IIa
6	CONVEX ARRAY TRANSDUCER	PVT-375MV	Class IIa
7	CONVEX ARRAY TRANSDUCER	PVT-375SC	Class IIa
8	CONVEX ARRAY TRANSDUCER	PVT-382BT	Class IIa
9	CONVEX ARRAY TRANSDUCER	PVT-382MV	Class IIa
10	CONVEX ARRAY TRANSDUCER	PVT-475BT	Class IIa
11	CONVEX ARRAY TRANSDUCER	PVT-674BT	Class IIa
12	CONVEX ARRAY TRANSDUCER	PVT-675MV	Class IIa
13	CONVEX ARRAY TRANSDUCER	PVT-675MVL	Class IIa
14	CONVEX ARRAY TRANSDUCER	PVT-681MV	Class IIa
15	CONVEX ARRAY TRANSDUCER	PVT-681MVL	Class IIa
16	CONVEX ARRAY TRANSDUCER	PVT-712BT	Class IIa
17	CONVEX ARRAY TRANSDUCER	PVT-745BTF	Class IIa
18	CONVEX ARRAY TRANSDUCER	PVT-745BTH	Class IIa
19	CONVEX ARRAY TRANSDUCER	PVT-745BTV	Class IIa
20	CONVEX ARRAY TRANSDUCER	PVT-770RT	Class IIa
21	CONVEX ARRAY TRANSDUCER	PVT-781VT	Class IIa
22	CONVEX ARRAY TRANSDUCER	PVT-781VTE	Class IIa
23	ENDOCAVITARY TRANSDUCER	PVL-715RST	Class IIa
24	LINEAR ARRAY TRANSDUCER	PLT-308P	Class IIa
25	LINEAR ARRAY TRANSDUCER	PLT-704SBT	Class IIa
26	LINEAR ARRAY TRANSDUCER	PLT-705BT	Class IIa
27	LINEAR ARRAY TRANSDUCER	PLT-705BTF	Class IIa
28	LINEAR ARRAY TRANSDUCER	PLT-705BTH	Class IIa
29	LINEAR ARRAY TRANSDUCER	PLT-1005BT	Class IIa
30	LINEAR ARRAY TRANSDUCER	PLT-1202BT	Class IIa
31	LINEAR ARRAY TRANSDUCER	PLT-1202S	Class IIa
32	LINEAR ARRAY TRANSDUCER	PLT-1204BT	Class IIa
33	LINEAR ARRAY TRANSDUCER	PLT-1204MV	Class IIa
34	MULTIPLANE TRANSESOPHAGEAL TRANSDUCER	PET-508MA	Class IIa
35	MULTIPLANE TRANSESOPHAGEAL TRANSDUCER	PET-511BTM	Class IIa

No	Description	Model	Classification
36	MULTIPLANE TRANSESOPHAGEAL TRANSDUCER	PET-512MA	Class IIa
37	MULTIPLANE TRANSESOPHAGEAL TRANSDUCER	PET-512MC	Class IIa
38	MULTIPLANE TRANSESOPHAGEAL TRANSDUCER	PET-512MD	Class IIa
39	LINEAR ARRAY TRANSDUCER	PET-805LA	Class IIa
40	CW DOPPLER PENCIL TRANSDUCER	PC-20M	Class IIa
41	CW DOPPLER PENCIL TRANSDUCER	PC-50M	Class IIa
42	SONO COUPLER	UACK-003A	Class IIa
43	SONO COUPLER	UACK-004A	Class IIa
44	BIOPSY ADAPTER	UAGL-001AHA	Class IIa
45	BIOPSY ADAPTER	UAGL-002AHA	Class IIa
46	BIOPSY ADAPTER	UAGL004A	Class IIa
47	BIOPSY ADAPTER	UAGL-015A	Class IIa
48	BIOPSY ADAPTER	UAGV020A	Class IIa
49	BIOPSY ADAPTER	UAGV-023A	Class IIa
50	BIOPSY ADAPTER	UAGV-024A	Class IIa
51	BIOPSY ADAPTER	UAGV-027A	Class IIa
52	BIOPSY ADAPTER	UAGV-028A	Class IIa
53	BIOPSY ADAPTER	UAGV-029A	Class IIa
54	BIOPSY ADAPTER	UAGV-030A	Class IIa
55	BIOPSY ADAPTER	UAGV-031A	Class IIa
56	BIOPSY ADAPTER	UAGV-032A	Class IIa
57	BIOPSY ADAPTER	UAGV-033A	Class IIa
58	BIOPSY ADAPTER	UAGV-034A	Class IIa
59	BIOPSY ADAPTER	UAGV-035A	Class IIa
60	Water Bag	UAWB-021A	Class IIa
61	Water Bag	UAWB-022A	Class IIa

Classification: Refer to the Article 9 of MDD

End of table