CANON MEDICAL SYSTEMS CORPORATION

Made For life

REF. NO. DQM30-92538*I

DECLARATION OF CONFORMITY

MANUFACTURER

CANON MEDICAL SYSTEMS CORPORATION
1385, Shimoishigami, Otawara-Shi, Tochigi 324-8550, JAPAN

AUTHORIZED REPRESENTATIVE

CANON MEDICAL SYSTEMS EUROPE BV
Zilverstraat 1, 2718 RP Zoetermeer, THE NETHERLANDS

MEDICAL DEVICE

Generic name:	Diagnostic Ultrasound System
Model:	TUS-AI700 (Aplio i700) (See attached sheet: Appendix 1)
Classification:	Class IIa (Article 9; Rule 10 ANNEX IX)
Given number of products:	This Declaration of Conformity is related to each Product release document.
Standards Applied:	EN 60601-1:2006+A1:2013, EN 60601-1-2:2015, EN 60601-1-6:2010+A1:2015, EN 60601-2-37:2008+A1:2015, EN 62304:2006+A1:2015, EN 62366:2008+A1:2015, EN 1041:2008, EN ISO 10993-1:2009/AC:2010, EN ISO 10993-5:2009, EN ISO 10993-7:2008/AC:2009, EN ISO10993-10:2013 EN ISO 11135-1:2007, EN ISO13485:2016/AC:2016, EN ISO 14937:2009, EN ISO14971:2012, EN ISO 15223-1:2016, EN ISO17664:2017, EN ISO 17665-1:2006

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.

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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: 22 March 2019

Signature: 

Koichi Mikami
Senior Manager
Quality & Environment Assurance Department
Quality, Safety and Regulation Center

Appendix 1

Applicable model:

Model Name	/Sup. Symbol
TUS-AI700	
TUS-AI700	/WC
TUS-AI700	/WK
TUS-AI700	/JH
TUS-AI700	/JK
TUS-AI700	/AE
TUS-AI700	/AK
TUS-AI700	/HE
TUS-AI700	/WA

Note: This DoC is applied to a product for EU and AU.