CANON MEDICAL SYSTEMS CORPORATION

Made For life

REF. NO. DQM30-92587*G

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:	CUS-AA550 (Aplio a550)
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 ISO 15223-1:2016, EN 1041:2008, EN ISO 10993-1:2009/AC:2010, EN ISO 10993-5:2009, EN ISO 10993-7:2008/AC:2009, EN ISO 10993-10:2013, EN ISO 11135-1:2007, EN ISO 13485:2016/AC:2016, EN ISO14937:2009, EN ISO 14971:2012, EN ISO 17664:2017, 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 COMMISSION DELEGATED DIRECTIVE (EU) 2015/863 of 31 March 2015 amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances. 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+(EU) 2015/863 is supported by EC quality system approval certification registration number HD 60143874 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: 25 May 2021

Signature: Fumiaki Teshima

Fumiaki Teshima
Senior Manager
Quality Assurance Department
Quality, Safety and Regulation Center