

DECLARATION OF CONFORMITY

MANUFACTURER

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

AUTHORIZED REPRESENTATIVE

CANON MEDICAL SYSTEMS EUROPE B.V.
Zilverstraat 1, 2718 RP Zoetermeer, THE NETHERLANDS

MEDICAL DEVICE

Generic name: Whole Body Computed Tomography Scanner

Model: TSX-305A (Aquilion ONE)
(See attached sheet: Appendix 1)

Classification: Class IIb (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/AC:2014,
EN 60601-1-2:2015, EN 60601-1-3:2008+A1:2013/AC:2014,
EN 60601-1-6:2010+A1:2015, EN IEC 60601-2-28:2019,
EN 60601-2-44:2009+A1:2012+A2:2016, EN 60825-1:2007,
EN 62304:2006/AC:2008, 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 14971:2012,
EN ISO 13485:2016/AC:2018, EN ISO 17664:2017
(*): This standard is applied for V10.0 or later.

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.



CANON MEDICAL SYSTEMS CORPORATION

Made For life

REF. NO. DQX70-92374*N

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 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

Appendix 1

Applicable model:

Model	/Sup. Symbol
TSX-305A	/4C
TSX-305A	/4F
TSX-305A	/4K
TSX-305A	/4N
TSX-305A	/5C
TSX-305A	/5F
TSX-305A	/5K
TSX-305A	/5N