

## 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-303B (Aquilion Prime SP)  
(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,  
EN 60601-1-2:2015, EN 60601-1-3:2008+A1:2013,  
EN 60601-1-6:2010+A1:2015, EN 60601-2-28:2010,  
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:2016, EN ISO 17664:2017  
(\* See attached sheet: Appendix 1)

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.

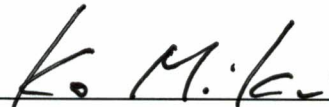
REF. NO. DQX70-92386\*J

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: 27 November 2019

Signature:



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Koichi Mikami

Senior Manager

Quality &amp; Environment Assurance Department

Quality, Safety and Regulation Center

**Appendix 1**

Applicable model:

Model	/Sup. Symbol
TSX-303B	/1C (*1)
TSX-303B	/1F (*1)
TSX-303B	/1K (*1)
TSX-303B	/1N (*1)
TSX-303B	/5C (*2)
TSX-303B	/5F (*2)
TSX-303B	/5K (*2)
TSX-303B	/5N (*2)

(\*1) EN 62304:2006/AC:2008 is applied only for TSX-303B /1.

(\*2) EN 62304:2006+A1:2015 is applied only for TSX-303B /5.