

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.

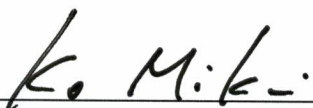
REF. NO. DQX70-92386*I

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: 23 August 2019

Signature: _____



Koichi Mikami

Senior Manager

Quality & 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.