



EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 740247 R000

Manufacturer: Canon Medical Systems Corporation

Address:

1385, Shimoishigami Otawara-shi Tochigi 324-8550 Japan

Single Registration Number: JP-MF-000011499

EU Authorised Representative: Canon Medical Systems Europe B.V.

Address:

Bovenkerkerweg 59 1185 XB Amstelveen The Netherlands

Scope: See attached Device Schedule

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2021-11-25** Starting Validity Date: **2023-07-26**

Current Issue Date: **2023-07-26** Expiry Date: **2026-11-24**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.





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Device Schedule: Class III and Class IIb devices

Class IIb	Intended purpose	
Computed Tomography Scanning System	This device is intended to acquire cross-sectional images of any part of the anatomy using X-rays and to provide physicians with such images for diagnostic use.	
Interventional Angiography System	This system is a diagnostic X-ray system designed for multidirectional observation of the flow of contrast medium injected into the blood vessels of a patient.	

Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification	
Magnetic Resonance Imaging System;	Class IIa	
Diagnostic Ultrasound system;		
Transducer for Diagnostic Ultrasound System		
Biopsy Adapter	Class IIa	16 60 A 1
Workstation Software for Diagnostic System	Class IIa	22

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate. Verification@bsigroup.com)

Date	Reference number	Action	
2021-11-25	3331175	Issued.	
2022-08-16	3730628	Amended - Addition of Legal Manufacturer's Single Registration Number. Supplemented - Addition of device category Computed Tomography Scanning System.	
2023-04-21	3913633	Supplemented - Addition of device category Diagnostic Ultrasound system, Transducers for Diagnostic Ultrasound System, and Biopsy Adapter Supplemented - Addition of device group Interventional Angiography System.	
2023-05-26	30000825	Supplemented - Addition of device category Workstation Software for Diagnostic System.	
Current	3891160	Amended – Change of authorised representative address to "Bovenkerkerweg 59, 1185 XB Amstelveen, The Netherlands".	

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