By Royal Charter

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**

Current Issue Date: **2023-07-26**

Starting Validity Date: **2023-07-26**

Expiry Date: **2026-11-24**

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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; Diagnostic Ultrasound system; Transducer for Diagnostic Ultrasound System	Class IIa
Biopsy Adapter	Class IIa
Workstation Software for Diagnostic System	Class IIa

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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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