EU Quality Management System Certificate

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

MDR 745709 R000

Manufacturer: Circle Cardiovascular Imaging Inc.

Address:
Western Canadian Place - North Tower
Suite 1800, 707 8th Avenue SW
Calgary
Alberta
T2P 1H5
Canada

Single Registration Number: CA-MF-000011835

EU Authorised Representative: QDossier B.V.

Address:
Cartografenweg 28C
5141 MT
Waalwijk
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 Global Regulatory & Quality

First Issue Date: **2022-06-30**

Current Issue Date: **2024-12-06**

Starting Validity Date: **2024-12-06**

Expiry Date: **2027-06-29**

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

Device(s)	Risk Classification
CT/MRI Imaging Software	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
2022-06-30	3403463	Issued
2023-03-28	3854638	Amended – Change of EU Representative from Circle Cardiovascular Imaging B.V to QDossier B.V.
2024-08-08	30208077	Amended – Change of manufacturer address to Western Canadian Place - North Tower, Suite 1800, 707 8th Avenue SW, Calgary, Alberta, T2P 1H5, Canada. Change of EU Rep address to Cartografenweg 28C, 5141 MT, Waalwijk, The Netherlands.
Current	30317711	Supplemented – Consolidation of exiting device (TruPlan) and added device (cvi42), resulting in addition of device category CT/MRI Imaging Software

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