

# EU Quality Management System Certificate

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

## MDR 745709 R000

**Manufacturer:** Circle Cardiovascular Imaging Inc.

**Address:**

Suite 1100, 800 5th Avenue SW  
Calgary  
Alberta  
T2P 3T6  
Canada

**Single Registration Number:** CA-MF-000011835

**EU Authorised Representative:** Circle Cardiovascular Imaging B.V.

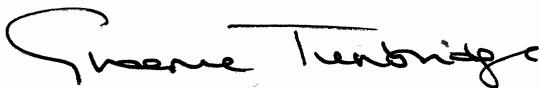
**Address:**

Single 250  
1016 AB  
Amsterdam  
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 and Class IIb implantable devices an 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 Issued: **2022-06-30**

Date: **2022-06-30**

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

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

Device(s)	Risk Classification
TruPlan	Class IIa



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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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### 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
Current	3403463	Issued



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

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A Member of the BSI Group of Companies.