

# EU Quality Management System Certificate

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

**MDR 757767**

**Manufacturer:** Canon Medical Informatics, Inc.

**Address:**

5850 Opus Parkway  
Suite 300  
Minnetonka  
Minnesota  
55343  
USA

**Single Registration Number:** US-MF-000020013

**EU Authorised Representative:** MDSS GmbH

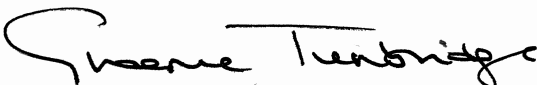
**Address:**

Schiffgraben 41  
Hannover  
30175  
Germany

**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 Issue Date: **2023-01-30**

Current Issue Date: **2023-01-30**

Starting Validity Date: **2023-01-30**

Expiry Date: **2028-01-29**

...making excellence a habit.™

# EU Quality Management System Certificate

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

## MDR 757767

### Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Vitrea View Software	Class IIa
Vitrea Advanced Visualization Software	Class IIa



First Issue Date: **2023-01-30**

Current Issue Date: **2023-01-30**

Starting Validity Date: **2023-01-30**

Expiry Date: **2028-01-29**

...making excellence a habit.™

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.

# EU Quality Management System Certificate

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

## MDR 757767

### 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	3537868	Issued



First Issue Date: **2023-01-30**

Current Issue Date: **2023-01-30**

Starting Validity Date: **2023-01-30**

Expiry Date: **2028-01-29**

...making excellence a habit.™

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.