

# EC CERTIFICATION

## QUALITY MANAGEMENT SYSTEM CERTIFICATE

### EU Regulation 2017/745 for Medical Devices, Annex IX Chapters I & III

We hereby declare that a conformity assessment based on a quality management system and technical documentation has been carried out following the requirements of EU Regulation 2017/745 for Medical Devices.

We certify that the documentation conforms to the relevant provisions of the aforementioned regulation, and the result entitles the organization to use the CE 2862 marking on the products listed below.

## Canon Medical Informatics A/S

Krumtappen 4, Etage 3, DK-2500 Valby, Denmark

Manufacturer SRN: DK-MF-000019622

### Scope:

Software Class IIa

**Certificate Number:**

28620128868

**Initial Certification Date:**

30 September 2022

**Date of Certification Decision:**

30 September 2022

**Certificate Issue Date:**

30 September 2022

**Certificate Expiry Date:**

23 April 2027



Brian Mather  
Certification Authority, MDR  
Intertek Medical Notified Body AB,  
Torshamnsgatan 43,  
Box 1103, SE-164 22 Kista, Sweden

Intertek Medical Notified Body AB is a Notified Body in accordance with the requirements set out in EU Regulation 2017/745 on medical devices, with the identification number 2862.



**PRODUCT LIST FOR CERTIFICATE**  
*See attached Product List*

**EXAMINATION AND TESTS PERFORMED**

Technical Assessment Report Reference	TD00027-01 Canon Medical Informatics A/S Vitrea Read
Audit Report Reference	Stage 1 audit ACTY-2020-449246
	Stage 1 audit ACTY-2021-518201
	Stage 2 audit ACTY-2020-449247

**CONDITIONS FOR OR LIMITATIONS TO VALIDITY OF CERTIFICATE**

None
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**CERTIFICATE HISTORY**

PRECEDING CERTIFICATE NUMBER	DATE OF ISSUE	IDENTIFICATION OF CHANGES

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## PRODUCT LIST FOR CERTIFICATE

**Issued to:** Canon Medical Informatics A/S  
**Certificate number:** 28620128868  
**Certificate valid from:** 2022-09-30

**Product List Issue Date:**  
23 February 2023

Product	Classification and EMDN	Intended use <sup>1</sup>	Date Added
Software			
<i>Basic UDI-DI: 628105VitreaRead0017Q</i>			
Vitrea Read	Class IIa		2022-09-30



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<sup>1</sup>The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

