EC CERTIFICATION

EU Quality Management System Certificate

Regulation (EU) 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 Regulation (EU) 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.

AGFA HealthCare N.V.

Septestraat 27, BE-2640 Mortsel, Belgium

Manufacturer SRN: BE-MF-000000909

Scope:

Software for imaging, radiology and clinical information

Certificate Number:
28620117074

Revision:
01

Initial Certification Date:
21 August 2021

Certificate Decision Date:
25 May 2026

Certificate Issue Date:
1 June 2026

Certificate Expiry Date:
31 May 2031

Mikael Hagelin
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

Audit report reference	**Re-certification - ACTY-2021-472724**
Technical assessment reference	**TD00003-002 - Enterprise Imaging XERO Viewer**

CONDITIONS FOR OR LIMITATIONS TO VALIDITY OF CERTIFICATE

None

CERTIFICATE HISTORY

CERTIFICATE NUMBER	DATE OF ISSUE	IDENTIFICATION OF CHANGES
28620117074	21 August 2021	Initial certificate
28620117074-01	1 June 2026	Re-certification

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PRODUCT LIST FOR CERTIFICATE

Issued to: AGFA HealthCare N.V.

Certificate number: 28620117074-01

Certificate valid from: 2026-06-01

Product list issue date:
25 May 2026

Product	Classification and EMDN	Intended use[1]	Date Added
Software for imaging, radiology and clinical information			
Basic UDI-DI: 05400874EID000703X9			
8.x - Enterprise Imaging Desktops	Class IIa Z110603		2021-08-25
Basic UDI-DI: 05400874EIX0007109V			
8.x - Enterprise Imaging XERO Viewer	Class IIa Z110603		2021-08-25

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[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.