

# **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.

# Agfa NV

Septestraat 27, BE-2640 Mortsel, Belgium

Manufacturer SRN: BE-MF-000000571

#### Scope:

- Imaging devices utilizing ionizing radiation for general, static and dynamic radiography

- Software for X-Ray systems

Certificate Number: 28620125060

Revision: 01

Initial Certification Date: 21 June 2022

**Date of Certification Decision:** 14 September 2023

**Certificate Issue Date:** 14 September 2023

Certificate Expiry Date: 31 May 2027

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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.





In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organisation maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at <u>certificate validation@intertek.com</u> or by scanning the code to the right with a smartphone. The certificate remains the property of Intertek, to whom it must be returned upon request





#### **PRODUCT LIST FOR CERTIFICATE**

See attached Product List

#### **EXAMINATION AND TESTS PERFORMED**

Technical Assessment Report Reference	TD0004-01 Agfa NV, DR800
Audit Report Reference	N/A

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

None

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Intertek Medical Notified Body AB is a Notified B**GAR 1** accordance with the requirements set out in EU **R 1** 2017/745 on medical devices, with the identification of the set 2862.



#### **CERTIFICATE HISTORY**

whom it must be returned upon request

PRECEDING CERTIFICATE NUMBER	DATE OF ISSUE	IDENTIFICATION OF CHANGES
28620125060	21 June 2022	Initial certificate

Page 2/2

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