

# 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 Mortselsel, 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

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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.

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**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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**CERTIFICATE HISTORY**

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

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