

# CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

**AGFA NV**

including companies according to appendix

Main site: Septestraat 27, 2640 Mortsels, Belgium

*Additional sites according to appendix*

has been registered by Intertek as conforming to the requirements of

**ISO 13485:2016**  
**EN ISO 13485:2016**

The management system is applicable to:

Design, Manufacturing, Sales, Distribution (incl. Warehousing),  
Installation and Servicing of medical imaging products.

Note: Previously issued as certificates 0106172 and 0106173

**Certificate Number:**

0169189

**Revision:**

00

**Initial Certification Date:**

1 July 2018\*

**Date of Certification Decision:**

11 May 2023

**Certificate Valid Date:**

1 June 2023

**Certificate Expiry Date:**

31 May 2026



Ackred. nr. 10426  
Certifiering av ledningssystem  
ISO/IEC 17021-1



**Intertek**

**Brian Mather**

Certification Authority, Intertek Medical  
Notified Body AB

Intertek Medical Notified Body AB  
P.O. Box 1103, SE-164 22 Kista, Sweden



# APPENDIX

This appendix identifies the locations by the management system of

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## AGFA NV

This appendix is linked to certificate #0169189 and cannot be shown nor reproduced without it.

| Site Name                                     | Address                                                                                                  | Scope                                                                                              |
|-----------------------------------------------|----------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|
| Agfa NV – Mortsels                            | Septestraat 27, 2640 Mortsels, Belgium                                                                   | Design, Manufacturing, Sales, Distribution, Installation and Servicing of medical imaging products |
| Agfa-Gevaert HealthCare GmbH – Peißenberg     | Max-Planck- Str. 1, 82380 Peißenberg, Germany                                                            | Manufacturing, Installation and Servicing of medical imaging products.                             |
| Agfa-Gevaert HealthCare GmbH – Schrobenhausen | Bürgermeister-Götz-Str. 10, 86529 Schrobenhausen, Germany                                                | Manufacturing of medical imaging products.                                                         |
| Agfa Imaging Co., Ltd. – Wuxi                 | No.1 Workshop, 115# Plot, National Hi-Tech Industrial Development Zone, Wuxi, 214028 Jiangsu, P.R. China | Manufacturing of medical imaging products.                                                         |
| Agfa Australia Pty Ltd - Burwood East         | 5 Lakeside Drive, Burwood East, Victoria 3151.                                                           | Sales, Installation and Servicing of medical imaging products.                                     |
| Agfa Canada Inc. - Mississauga                | 2-5975 Falbourne St., Mississauga, Ontario L5R 3V8, Canada                                               | Sales, Installation and Servicing of medical imaging products.                                     |
| Agfa NV (French Branch) - Rueil Malmaison     | 21 Avenue de Colmar, 92565, Rueil Malmaison, France                                                      | Sales, Installation and Servicing of medical imaging products.                                     |
| Agfa HealthCare Germany GmbH - Düsseldorf     | Agfa HealthCare Germany GmbH - Düsseldorf                                                                | Sales, Installation and Servicing of medical imaging products.                                     |



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|                                                                |                                                                                                                                                                                       |                                                                                                   |
|----------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------|
| Agfa NV - Filiale Italiana - Milano                            | Via Massimo Gorki 69, 20092, Cinisello Balsamo, Milano, Italy                                                                                                                         | Sales, Installation and Servicing of medical imaging products.                                    |
| Agfa Healthcare UK Ltd – United Kingdom and Ireland - Uxbridge | 6-9 The Square, Stockley Park, Uxbridge, Middlesex, UB11 1FW, United Kingdom                                                                                                          | Sales, Installation and Servicing of medical imaging products.                                    |
| Agfa NV (Spółka Akcyjna) Oddział w Polsce - Warsaw             | Oxygen Park Budynek B, ul. Jutrzenki 137A, Warszawa, 02-231, Poland (Polska)                                                                                                          | Sales, Installation and Servicing of medical imaging products. (Incl. Shared Service Center)      |
| Agfa US Corporation - Carlstadt                                | 580 Gotham Parkway, Carlstadt, NJ 07072, USA                                                                                                                                          | Sales, Distribution (incl. Warehousing), Installation, and Servicing of medical imaging products. |
| Agfa Australia Pty Ltd                                         | 5 Lakeside Drive, Burwood East, Victoria 3151.                                                                                                                                        | Sales, Installation and Servicing of medical imaging products.                                    |
| Agfa NV, Sucursal en España                                    | C/. Gaspar Fàbregas i Roses, 81 - 3ª plta., 8950, Esplugues de Llobregat (Barcelona), Spain                                                                                           | Sales, Installation and Servicing of medical imaging products.                                    |
| Agfa NV, Sucursal em Portugal                                  | Rua dos Malhoes, Centro Regus, Edifício D. Pedro I Distrito: Lisboa Concelho: Oerias Freguesia: Oerias e S. Juliao da Barra, Paço de Arcos e Caxias, 2770 071 Paço de Arcos, Portugal | Sales, Installation and Servicing of medical imaging products.                                    |

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| Certificate Number:         | 0169189     |
| Initial Certification Date: | 1 July 2018 |
| Certificate Issue Date:     | 1 June 2023 |
| Certificate Expiry Date:    | 31 May 2026 |



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