

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

AGFA NV

Main site: Septestraat 27, 2640 Mortsel, Belgium

Additional sites according to appendix

has been registered by Intertek as conforming to the requirements of

EN ISO 13485:2016

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:

05

Initial Certification Date:

1 July 2018

Date of Certification Decision:

13 April 2026

Certificate Valid Date:

1 June 2026

Certificate Expiry Date:

31 May 2029



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



intertek

Mikael Hagelin

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 #0169189-05 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 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 - Neuilly-sur-Seine	Wojo Neuilly-sur-Seine, 88 Avenue Charles De Gaulle, 92200 Neuilly-sur-Seine, 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.
Agfa NV - Filiale Italiana - Milano	Via Milanese 20, 20099 Sesto San Giovanni, Milano, Italy	Sales, Installation and Servicing of medical imaging products.
Agfa Healthcare UK Ltd – United Kingdom and Ireland - Cambridge	515 Coldhams Lane, CB1 3JS Cambridge, Cambridgeshire, United Kingdom	Sales, Installation and Servicing of medical imaging products.



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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 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, Edificio D. Pedro I Distrito: Lisboa Concelho: Oerias Freguesia: Oeiras e S. Juliao da Barra, Paço de Arcos e Caxias, 2770 071 Paço de Arcos, Portugal	Sales, Installation and Servicing of medical imaging products.
AGFA SOUTH AFRICA (Pty) Ltd	Office Number C4, El Ridge Office Park Corner Elizabeth and Caravelle Roads Bartlett 1460 Boksburg - Gauteng South Africa	Sales, Installation and Servicing of medical imaging products.

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Certificate Number: 0169189-05
Initial Certification Date: 1 July 2018
Certificate Issue Date: 1 June 2026
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