

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:

01

Initial Certification Date:

1 July 2018*

Date of Certification Decision:

5 June 2025

Certificate Valid Date:

5 June 2025

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

Page 1

AGFA NV

This appendix is linked to certificate #0169189-01 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 – Schrobenehausen	Bürgermeister-Götz-Str. 10, 86529 Schrobenehausen, 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.



APPENDIX

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 - Cambridge	515 Coldhams Lane, CB1 3JS Cambridge, Cambridgeshire, 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, 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.

Page 2



APPENDIX

Page 3

Certificate Number:	0169189-01
Initial Certification Date:	1 July 2018
Certificate Issue Date:	5 June 2025
Certificate Expiry Date:	31 May 2026



Brian Mather

Certification Authority, Intertek Medical Notified Body AB

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

