

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

AGFA NV

including companies according to appendix

Main site: Septestraat 27, 2640 Mortsel, Belgium

Additional site according to appendix

has been registered by Intertek as conforming to the requirements of

ISO 13485:2016

The management system is applicable to:

Design, manufacturing, distribution, installation and servicing of medical imaging solutions (radiology and printing devices, medical film)

*Previously certified by Intertek Certification AB to date 8 October 2020

Certificate Number:

0106173-00

Initial Certification Date:

1 July 2018*

Date of Certification Decision:

8 October 2020

Certificate Valid Date:

8 October 2020

Certificate Expiry Date:

31 May 2023



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 #0106173-00 and cannot be shown nor reproduced without it.

Development sites

Agfa-Gevaert HealthCare GmbH, Tegernseer Landstr. 161, 81539 München, Germany

Manufacturing sites

Agfa-Gevaert HealthCare GmbH, Bürgermeister-Götz-Str. 10, 86529 Schrobenhausen, Germany

Agfa-Gevaert HealthCare GmbH, Max-Planck- Str. 1, 82380 Peißenberg, Germany

Agfa-Gevaert HealthCare GmbH, Dr. Kisselmann Str. 1, 86971 Peiting, Germany

Sales and Service Units

Australia

Agfa Australia Pty Ltd, 12 Dalmore Drive, Scoresby, VIC 3179, Australia



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Belgium, Luxembourg

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Agfa NV, Septestraat 27, 2640, Mortsel, Belgium

Canada

Agfa Canada Inc., 2-5975 Falbourn St., Mississauga, Ontario L5R 3V8, Canada

France

Agfa NV (French Branch), Immeuble Optima, 27-35 rue Victor Hugo, 94853, Ivry-sur-Seine Cedex, France

Germany, Austria, Switzerland

Agfa HealthCare Germany GmbH, Paul-Thomas-Straße 58, 40599, Düsseldorf, Germany

AGFA NV, Zweigniederlassung Österreich, Diefenbachgasse 35, 1150, Vienna, Austria

AGFA, Mortsel/Belgien, Zweigniederlassung Dübendorf/Schweiz, Stettbachstrasse 7, CH-8600, Dübendorf, Switzerland

Greece

Agfa-Gevaert A.E.B.E, Acharnon 481, 14343 Nea Chalkidona (Athens), Greece



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Spain, Italy, Portugal

Agfa NV, Sucursal en España, C/. Gaspar Fàbregas i Roses, 81 - 3^a plta., 8950, Esplugues de Llobregat (Barcelona), Spain

Agfa NV, Sucursal em Portugal, Rua dos Malhoes, Centro Regus, Edifício D. Pedro I Distrito: Lisboa Concelho: Oerias Freguesia: Oeiras e S. Juliao da Barra, Paço de Arcos e Caxias, n° 1 B Paiões, 2770 071 Paço de Arcos, Portugal

Agfa NV - Filiale Italiana, Via Massimo Gorki 69, 20092, Cinisello Balsamo, Milano, Italy

United Kingdom, Ireland

Agfa Healthcare UK Ltd, 6-9 The Square, Stockley Park, Uxbridge, Middlesex, UB11 1FW, United Kingdom

USA

Agfa US Corporation, 10 South Academy Street, Greenville, South Carolina 29601, USA

Agfa US Corporation, 580 Gotham Parkway, Carlstadt, NJ 07072, USA



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