

# 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

**Revision:**

10

**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



**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 #0106173-10 and cannot be shown nor reproduced without it.

### 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 (Wuxi) Imaging Co., Ltd.** , No.1 Workshop, 115# Plot, National Hi-Tech Industrial Development Zone, Wuxi, 214028 Jiangsu, P.R. China

### Sales and Service Units

#### Australia

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

#### Canada

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



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## France

**Agfa NV (French Branch)**, 21 Avenue de Colmar, 92565, Rueil Malmaison, 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

## Spain, Italy, Portugal

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

**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

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



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## United Kingdom, Ireland

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

## Shared Service Center

### Poland

**Agfa NV (Spółka Akcyjna) Oddział w Polsce**, Oxygen Park Budynek B, ul. Jutrzenki 137A, Warszawa, 02-231, Poland (Polska)

## Sales and Service Center, Warehouse and distribution

### USA

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



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Certificate Number: 0106173-10  
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