

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

AGFA HEALTHCARE N.V.
including companies according to appendix

Main site: Septestraat 27, 2640 Mortsel, Belgium

Additional sites according to appendix

has been registered by Intertek as conforming to the requirements of

ISO 13485:2016

The management system is applicable to:

Design, development, installation, and servicing of healthcare IT solutions

*Previously certified by Intertek Certification AB to date 14 October 2020

Certificate Number:

0107014

Revision:

04

Initial Certification Date:

3 August 1990*

Date of Certification Decision:

28 June 2023

Certificate Valid Date:

28 June 2023

Certificate Expiry Date:

31 May 2026



Akkred. 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 HEALTHCARE N.V.

This appendix is linked to certificate #0107014-04 and cannot be shown nor reproduced without it.

Design & Development of healthcare IT solutions

Agfa HealthCare N.V., Moutstraat 100, 9000 Ghent, Belgium

Agfa HealthCare Ges.m.b.H., Diefenbachgasse 35, 1150 Vienna, Austria

Agfa HealthCare IT (Shanghai) Co. Ltd., 15F No.388 West Nanjing Road, CIRO's Plaza,
200003Shanghai, People's Republic of China

Design & Development of healthcare IT solutions (including Sales, Installation and Servicing)

Agfa HealthCare Inc., 375 Hagey Boulevard, Waterloo, Ontario N2L 6R5, Canada

Sales, Installation and Servicing of healthcare IT solutions

Australia

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



APPENDIX

Belgium, Luxembourg

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Agfa HealthCare N.V., Septestraat 27, 2640, Mortsel, Belgium

Spain, Italy

Agfa HealthCare Spain S.A.U., Calle Gaspar Fabregas i Roses 81, planta baja, 8950 Esplugues de Llobregat (Barcelona), Spain

Agfa-Gevaert SpA, Via Massimo Gorki 69, 20092 Cinisello Balsamo, Milano, Italy

Sweden, Denmark

Agfa HealthCare Sweden AB, Borgarfjordsgatan 14, 6.tr, SE-164 40 Kista, Sweden

Agfa HealthCare Denmark A/S, Lyngbyvej 20, 2100 Kobenhavn, Denmark

The Netherlands

Agfa-Gevaert B.V., Polakweg 10-11, 2288 Rijswijk, The Netherlands

Saudi Arabia

Agfa HealthCare Saudi Arabia Ltd., Al-Aqaria 2 Office No. 326, 12244 Olayia, Riyadh, Saudi Arabia



APPENDIX

United Kingdom, Ireland

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Agfa Healthcare IT UK Ltd, 1 Hawthorn Park, Coal Road, Leeds, LS14 1PQ, United Kingdom

USA

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

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

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