

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

AGFA HEALTHCARE N.V.

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, development, installation and servicing of healthcare IT solutions

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

Certificate Number:

0107012

Revision:

09

Initial Certification Date:

15 March 2015*

Date of Certification Decision:

01 June 2026

Certificate Valid Date:

01 June 2026

Certificate Expiry Date:

31 May 2029



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 HEALTHCARE N.V.

This appendix is linked to certificate #0107012-09 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 NV (Branch Austria), 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, Suite 2, 5 Lakeside Drive, Burwood East, VIC 3151, Australia



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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 HealthCare Italy SpA., Via Massimo Gorki 69, 20092 Cinisello Balsamo, Milano, Italy

Sweden, Denmark

Agfa HealthCare Sweden AB, Regus, Kista One, Kistagången 20b, E-164 40 Kista, Stockholm

Agfa HealthCare Denmark A/S, Arne Jacobsens Allé 15, mezz., 2300 København S, Denmark

The Netherlands

Agfa HealthCare Netherlands BV., 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



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United Kingdom, Ireland

Agfa Healthcare IT UK Ltd, 3 Hawthorn Park, Coal Road, Leeds, LS14 1PQ, United Kingdom

USA

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

Poland

Agfa Sp. z o.o., ul. Jutrzenki 137 A, 02-231 Warszawa, Poland



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