

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Agfa HealthCare N.V.

(F004334)

Main Site: Septestraat 27, Mortsel, 2640, Belgium

has been registered by Intertek, an MDSAP recognized auditing organization, as conforming to the requirements of:

ISO 13485:2016

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6)

Brazil: Federal Law n. 6360/76; RDC ANVISA n. 16/2013; RDC ANVISA n. 23/2012; RDC ANVISA n. 67/2009; RDC ANVISA n. 56/2001

Canada: Medical Devices Regulations – Part 1- SOR 98/282

United States: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 (Subparts A to D)

The management system is applicable to:

Design, manufacturing, installation and servicing of Picture Archiving and Communication Systems (PACS) and Image processing software for the hospital enterprise.

Certificate Number:

0077516-04

Initial Certification Date:

2006-07-11

Certification Effective Date:

2023-07-10

Certification Expiry Date:

2026-07-10



intertek

A handwritten signature in black ink, appearing to read "Calin Moldovean", written over a horizontal line.

Calin Moldovean

President, Business Assurance

Intertek Testing Services NA, Inc.
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