

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: RDC ANVISA n. 665/2022, RDC ANVISA n. 551/2021, RDC ANVISA n. 67/2009

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

Revision Level: 05

Initial Certification Date:

2018-07-01

Certification Effective Date:

2025-06-02

Certification Expiry Date:

2026-07-10



intertek

Rathin Grover

President, Business Assurance

Intertek Testing Services NA, Inc.

4700 Broadmoor SE, Suite 200

Kentwood, MI, USA, 49512

