UKCA CERTIFICATE

FULL QUALITY ASSURANCE SYSTEM

Part II of The Medical Devices Regulations 2002, Annex II excluding Section 4 [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002]

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of UK Statutory Instrument 2002 No. 618, as amended, to which the undersigned is subjected.

We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned legislation, and the result entitles the organisation to use the UKCA 8532 marking on those products listed below.

AGFA HealthCare N.V.

Septestraat 27, BE-2640 Mortsel, Belgium

Scope:

Software for imaging, radiology and clinical information

For further identification of the products covered, see the attached product list/product schedule

Certificate Number:
85320173327
Revision
01
Initial Certification Date:
25 April 2024
Date of Certification Decision:
25 May 2026
Certificate Valid Date:
1 June 2026
Certificate Expiry Date:
31 May 2031

Sharmila Gardner
Head of UK Approved Body
Intertek Medical Notified Body UK Ltd
Academy Place, 1-9 Brook Street
Brentwood, Essex CM14 5NQ
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The certification is subject to the organization maintaining their system in compliance with the regulations stated in this certificate, allowing regular assessments and following the contracted requirements of the UK Approved Body.

Intertek Medical Notified Body UK Ltd is a UK Approved Body according to UK SI 2002 No. 618 on medical devices, with identification number 8532.

PRODUCT LIST FOR CERTIFICATE

Issued to: AGFA HealthCare N.V.

Certificate number: 85320173327-01

Certificate valid from: 2026-06-01

Product list issue date:
25 May 2026

Product	Classification and GMDN	Intended use[1]	Date Added
Software for imaging, radiology and clinical information			
Product group: Software for imaging, radiology and clinical information			
8.x - Enterprise Imaging Desktops	Class IIa 41670		2024-04-25
8.x - Enterprise Imaging XERO Viewer	Class IIa 41670		2024-04-25

Sharmila Gardner (Head of Approved Body)
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[1]The intended use is only included for Class IIb and Class III devices.