

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 NV

Septestraat 27, BE-2640 Mortsel, Belgium

Scope:

- Imaging devices utilizing ionizing radiation for general, dynamic and static use,
- Software for X-Ray systems

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

Certificate Number: 85320169190 Revision 01 Initial Certification Date: 05 March 2024 Date of Certification Decision: 05 March 2024 Certificate Valid Date: 05 March 2024 Certificate Expiry Date: 31 May 2028

Sharmila Gardner Head of UK Approved Body Intertek Medical Notified Body UK Ltd Academy Place, 1-9 Brook Street Brentwood, Essex CM14 5NQ imnb@intertek.com

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.



In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organisation maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at <u>certificate validation@intertek.com</u> or by scanning the code to the right with a smartphone. The certificate remains the property of Intertek, to whom it must be returned upon request.

