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.

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

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

Sharmila Gardner
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Intertek Medical Notified Body UK Ltd
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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.