# Declaration of Conformity

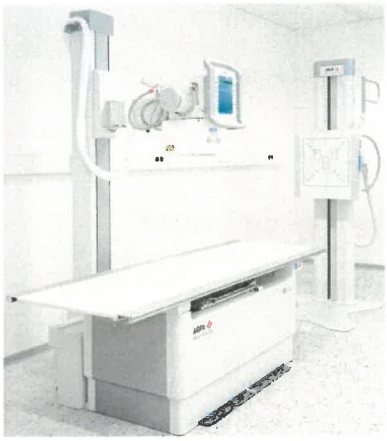
## Agfa NV

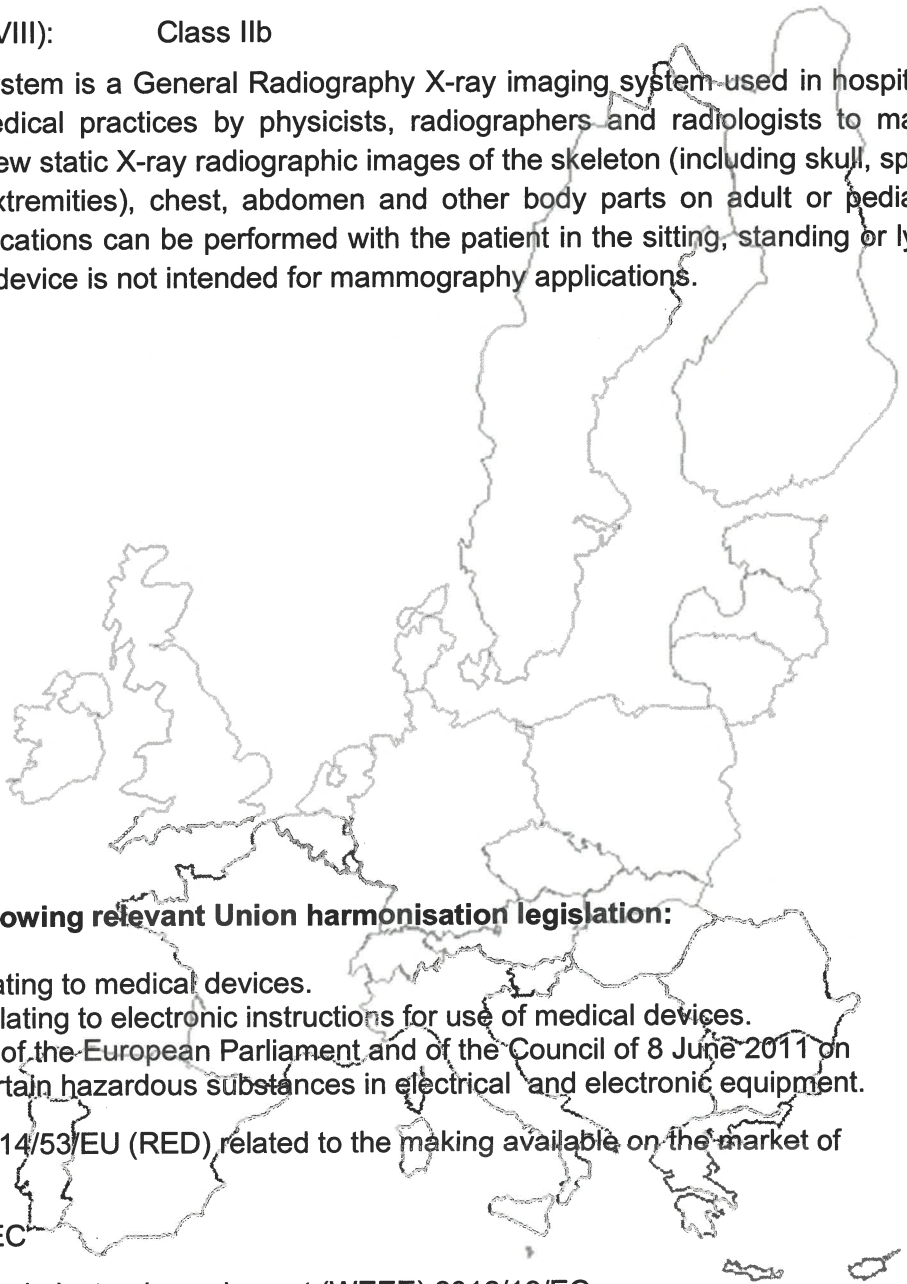
SRN Manufacturer BE-MF-000000571
Septestraat 27, 2640 Mortsel, Belgium

**Declare under our sole responsibility that the device**

| | |
|---|---|
| Basic UDI-DI: | 5414904272848YZ |
| Product Name: | **DR 400** |
| Product Code: | 5520/100 & 5520/150 & 5520/200 |
| Risk Class (according Annex VIII): | Class IIb |

Intended use: The DR 400 system is a General Radiography X-ray imaging system used in hospitals, clinics and medical practices by physicists, radiographers and radiologists to make, process and view static X-ray radiographic images of the skeleton (including skull, spinal column and extremities), chest, abdomen and other body parts on adult or pediatric patients. Applications can be performed with the patient in the sitting, standing or lying position. This device is not intended for mammography applications.





**is in conformity with the following relevant Union harmonisation legislation:**

Regulation (EU) 2017/745 relating to medical devices.
Regulation (EU) 2021/2226 relating to electronic instructions for use of medical devices.
Directive 2011/65/EU (RoHS) of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

Radio Equipment Directive 2014/53/EU (RED) related to the making available on the market of radio equipment.

Machinery directive 2006/42/EC

Directive on waste electrical and electronic equipment (WEEE) 2012/19/EC

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**and that the device is in conformity with the following common specification and / or harmonized standards and / or other normative documents:**

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|---|---|
| EN ISO 13485 | Quality management systems, requirements for regulatory purposes. |
| EN ISO 14971 | Medical devices – Application of risk management to medical devices. |
| EN ISO 15223-1 | Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements. |
| EN 60601 | Series Medical Electrical Equipment |
| - Part 1 | General requirements for safety and essential performance |
| - Part 1-2 | Collateral standard: electromagnetic compatibility – requirements and tests. |
| - Part 1-3 | General requirements for safety and essential performance -- Collateral Standard: Radiation protection in diagnostic X-ray equipment. |
| - Part 1-6 | Collateral standard: usability. |
| - Part 2-28 | Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures (IEC 60601-2-28) |
| - Part 2-54 | Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy (IEC 60601-2-54) |
| EN 62304 | Medical device software – software life cycle processes. |
| EN 62366 | Medical devices -- Application of usability engineering to medical devices |

**and that the following Notified Body performed the conformity assessment as described below and issued the EC Certificate:**

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| Notified Body Name: | Intertek Medical Notified Body AB (IMNB AB) |
| Address: | P.O. Box 1103, SE-164 22 Kista |
| Country: | Sweden |
| Identification number: | 2862 |
| Conformity Assessment: | Annex IX of 2017/745 Medical Device Regulation |
| EC Certificate number: | 28620125060 |

Date of issue: 24/04/2025

Koen Vervoort
Head of Quality Assurance & Regulatory Affairs
Agfa NV