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:	5414904272718YK
Product Name:	**DX-D 300**
Product Code:	8207/050
Risk Class (according Annex VIII):	Class IIb

Intended use: The DX-D 300 system is an integrated 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, pediatric or neonatal 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.

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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:

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, labelling and information to be supplied - General requirements
IEC 60601	Series Medical Electrical Equipment (harmonized standard)
- Part 1 :	General requirements for basic safety and essential performance (IEC 60601-1)
- Part 1-2 :	Collateral standard: electromagnetic disturbances – requirements and tests (IEC 60601-1-2)
- Part 1-3 :	Collateral Standard: Radiation protection in diagnostic X-ray equipment (IEC 60601-1-3)
- Part 1-6 :	Collateral standard: usability (IEC 60601-1-6)
- Part 2-28 :	Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis (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)
IEC 62304	Medical device software – software life cycle processes (harmonized standard)
IEC 62366	Medical devices - Application of usability engineering to medical devices (harmonized standard)
EN ISO 10993	Biological evaluation of medical devices

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

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
Global Head of Quality Assurance & Regulatory Affairs
Agfa NV

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