Declaration of Conformity

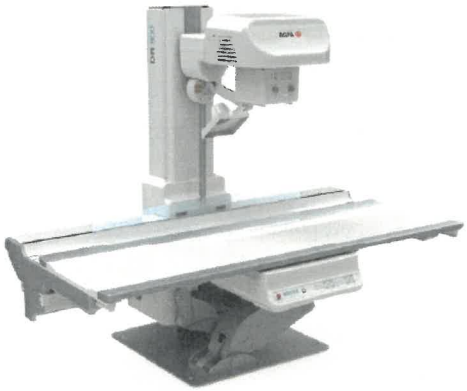
Agfa NV

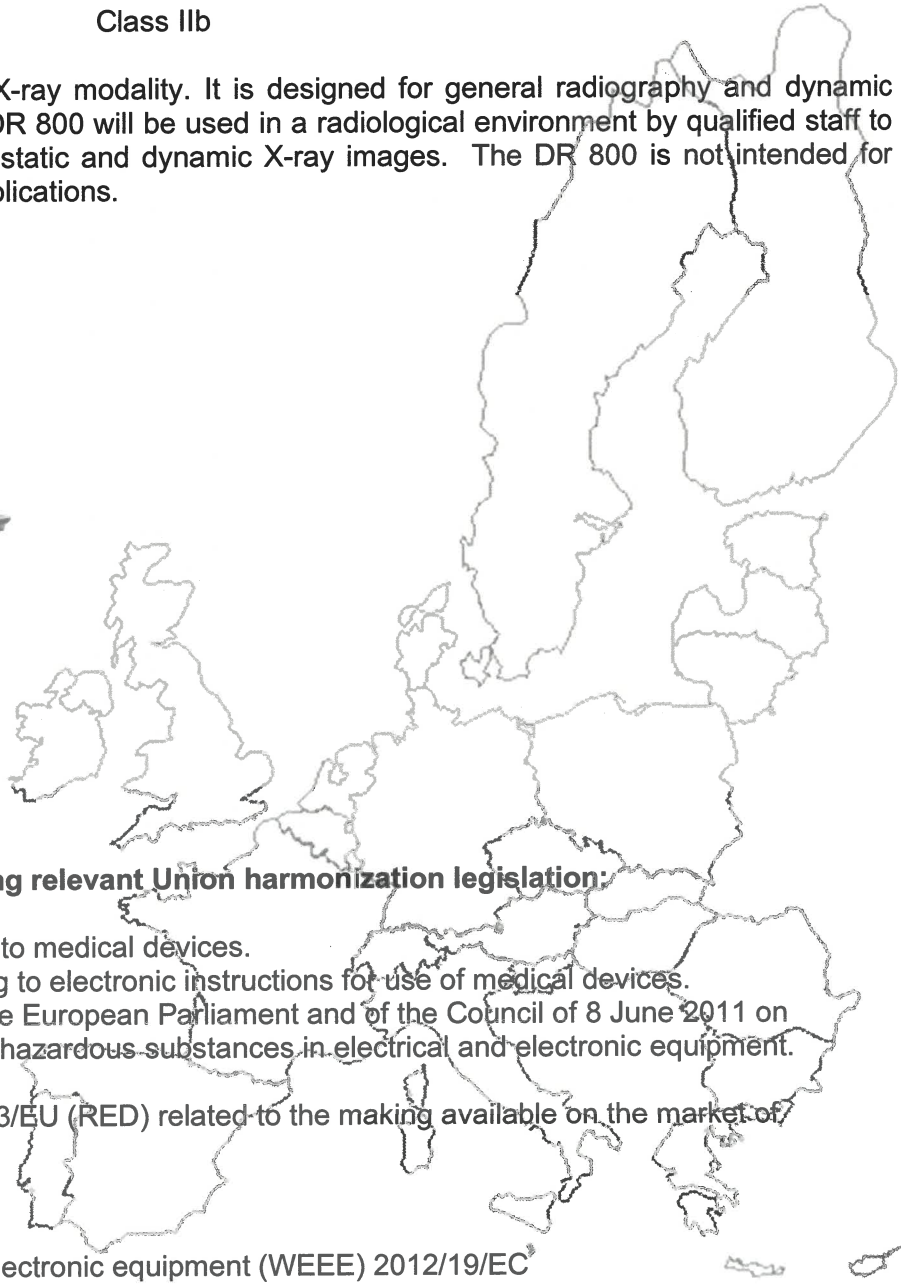
SRN Manufacturer BE-MF-000000571
Septestraat 27, 2640 Mortsel, Belgium

Declare under our sole responsibility that the device

Basic UDI-DI:	541490427224YK
Product Name:	**DR 800**
Product Code:	6010/200
Risk Class (according Annex VIII):	Class IIb

Intended use:. The DR 800 is a X-ray modality. It is designed for general radiography and dynamic applications. The DR 800 will be used in a radiological environment by qualified staff to capture and route static and dynamic X-ray images. The DR 800 is not intended for mammography applications.





is in conformity with the following relevant Union harmonization 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:

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 ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN 60601	Series Medical Electrical Equipment
- Part 1	General requirements for basic safety and essential performance
- Part 1-2	Collateral standard: electromagnetic disturbances – requirements and tests.
- Part 1-3	Collateral Standard: Radiation protection in diagnostic X-ray equipment.
- Part 1-6	Collateral standard: usability.
- Part 2-54	Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy
EN 62304	Medical device software – software life cycle processes
EN 62366-1	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:

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

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