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:	5414904272749YW
Product Name:	**Drystar AXYS**
Product Code:	5367/100
Risk Class (according Annex VIII):	Class I

Intended use: The Drystar AXYS is a dry digital tabletop printer for producing medical diagnostic images. He can print multiple formats of blue-based (8x10 inch, 10x12 inch, 11x14 inch, 14x14 inch and 14x17 inch), clear-based (8x10 inch, 10x12 inch, 11x14 inch, 14x14 inch and 14x17 inch) or Mammo film (8x10 inch, 10x12 inch, 11x14 inch) and offers crisp, dense grayscale images. The Drystar AXYS can be used for general radiography and optionally for the mammography application. The Drystar AXYS is designed for high throughput and for use as a central printer.

is in conformity with the following relevant Union harmonisation legislation:

Regulation (EU) 2017/745 relating to 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.

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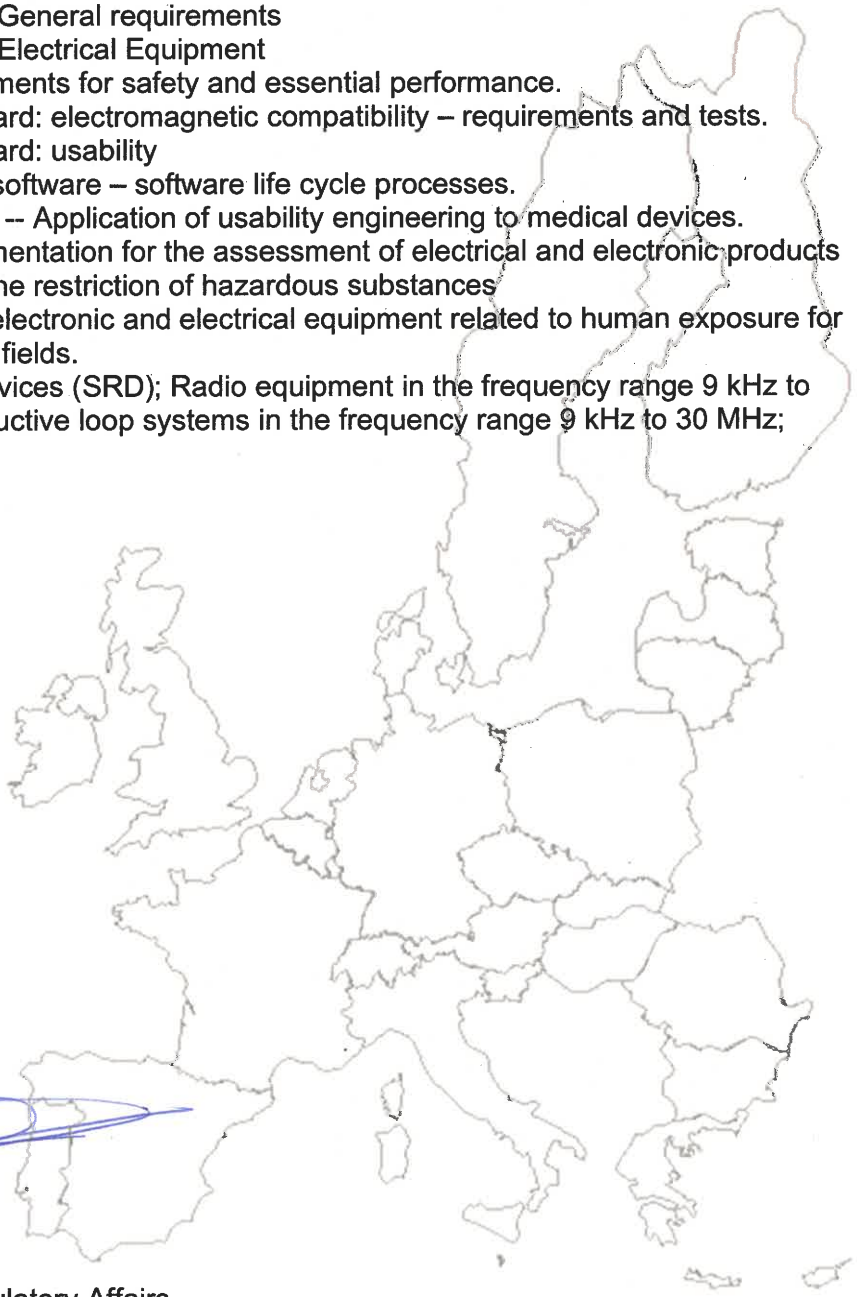
and that the device is in conformity with the following common specification and / or harmonized standards and / or other normative documents:

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
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 1-6	Collateral standard: usability
EN 62304	Medical device software – software life cycle processes.
EN 62366	Medical devices -- Application of usability engineering to medical devices.
EN 50581	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances
EN 62311	Assessment of electronic and electrical equipment related to human exposure for electromagnetic fields.
EN 300 330	Short Range Devices (SRD); Radio equipment in the frequency range 9 kHz to 25 MHz and inductive loop systems in the frequency range 9 kHz to 30 MHz;



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Koen Vervoort
Head of Quality Assurance & Regulatory Affairs
Agfa NV

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