PHILIPS

EU Declaration of Conformity

Manufacturer name / address
Philips Medical Systems Nederland B.V.
Veenpluis 4-6, 5684 PC Best,
The Netherlands
Commercial Register Eindhoven No. 17060498

Additional *manufacturing site name/address*
Not applicable

This declaration of conformity is issued under the sole responsibility of the manufacturer. The device covered by the present declaration is in conformity with all regulations below and other relevant Union legislation.

Object of the declaration:

Product Name:	Azurion 3 M12 Azurion 3 M15 Azurion 5 M12 Azurion 5 M20 Azurion 7 M12 Azurion 7 M20 Azurion 7 B12 Azurion 7 B20
Intended Purpose:	The Azurion series (within the limits of the used Operation Room table) are intended for use to perform: • Image guidance in diagnostic, interventional and minimally invasive surgery procedures for the following clinical application areas: vascular, non-vascular, cardiovascular and neuro procedures. • Cardiac imaging applications including diagnostics, interventional and minimally invasive surgery procedures. Additionally: • The Azurion series can be used in a hybrid Operation Room. • The Azurion series contain a number of features to support a flexible and patient centric procedural workflow.
Product designator:	R2.1
Product Part Number(s):	722 221 (Azurion 3 M12) 722 222 (Azurion 3 M15) 722 227 (Azurion 5 M12) 722 228 (Azurion 5 M20) 722 223 (Azurion 7 M12) 722 224 (Azurion 7 M20) 722 225 (Azurion 7 B12) 722 226 (Azurion 7 B20)
Control Indicator:	May 01 2020
Global Medical Device Nomenclature Code (GMDN) and Description:	37623 Stationary, angiographic, X-ray system, digital
Product Options/Accessories:	Accessories as described in the accompanying labeling documentation

The object of the declaration described above is in conformity with the following regulations:

EU Directive	**Council Directive 93/42/EEC of 14 June 1993 concerning medical Devices (as last amended by 2007/47/EC)**
Device Risk Classification	Class IIb based on Annex IX and Rule 10
NBOG Code	MD1302 Monitoring devices of vital physiological parameters.
Conformity Assessment Path	Annex II (excluding 4) Full Quality Assurance System
Name/Address/ID of Notified Body	DEKRA Certification B.V. Meander 1051 6825 MJ Arnhem

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	The Netherlands Notified Body ID 0344
EU Certificate Number	2079177CE01
Standards	The products listed above have been tested in a typical configuration as described in the Manufacturer's accompanying documentation, and are fully compliant with the product standards listed below.

Harmonized EN standards for 93/42/EEC (MDD)	Standard title
EN 60601-1: 2006/A1 :2013	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
EN 60601-1-2: 2015	Par 1-2: Collateral standard: Electromagnetic disturbances – Requirements and tests
EN 60601-1-3: 2008/A11:2016	Part 1-3: Collateral standard: Radiation protection in diagnostic X-ray equipment
EN 60601-1-6:2010	Part 1-6: Collateral standard: Usability
EN 60601-2-43:2010	Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures
EN 60601-2-54:2009	Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy
EN 62304: 2006+ C11:2008 + A1:2015	Medical device software — Software life-cycle processes
EN 62366:2008	Medical devices – Application of usability engineering to medical devices
EN ISO 14971:2012	Medical devices – Application of risk management to medical devices
EN ISO 15223-1:2016	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied
EN1041:2008	Information supplied by the manufacturer of medical devices

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EU Directive	***Directive 2011/65/EU 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*.**
Standards	The products listed above have been tested in a typical configuration as described in the Manufacturer's accompanying documentation, and are fully compliant with the product standards listed below.

Harmonized EN standards for 2011/65/EU (RoHS)	Standard title
EN50581:2012	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances
IEC63000:2016	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances

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EU Directive	***Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment***
Standards	The radio transmitting equipment was tested in accordance with the Radio Equipment Directive, and all essential radio test suites (as defined in the Essential Requirements) have been carried out. It fully complies with the standards listed below.

(Harmonized) Standards for 2014/53/EU (RED)	Standard title
EN 300 328 V2.1.1 (2016)	Wideband transmission systems; Data transmission equipment operating in the 2.4 GHz ISM band and using wide band modulation techniques; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU
EN 300 440 V2.1.1 (2017)	Short Range Devices (SRD); Radio equipment to be used in the 1 GHz to 40 GHz frequency range; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU
EN 301 489-1 V2.1.1 (2017) (Not harmonized)	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements. Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU and the essential requirements of article 6 of Directive 2014/30/EU
EN 301 489-1 V2.2.0 (2017) (Not harmonized)	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU and the essential requirements of article 6 of Directive 2014/30/EU
EN 301 489-3 V2.1.1 (2017) (Not harmonized)	Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 3: Specific conditions for Short-Range Devices (SRD) operating on frequencies between 9 kHz and 40 GHz. Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU
EN 301 489-17 V3.1.1 (2017) (Not harmonized)	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for Broadband Data Transmission Systems; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU
EN 62479:2010	Assessment of the compliance of low-power electronic and electrical equipment with the basic

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		restrictions related to human exposure to electromagnetic fields (10 MHz to 300 GHz)

Additional Information:

Quality Certificates Issued:	EN ISO 13485:2016 Certificate, valid until the 1st of February 2023 Certificate Number: 2079177

Signed for and on behalf of: Philips

Date of Issue: May 01 2020
Place of Issue: Best, The Netherlands
Printed Name: Michael Konings
Function: Director, Regulatory Affairs

Signature:

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Revision history

Revision Number	Revision Date	Author	Source	Changes/Comments
00	2020 May 1	Campbell Michelle	D-419303	Initial version

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