DECLARATION OF CONFORMITY

XEOS Medical, Ottergemsesteenweg-Zuid 808 Bus 358
Gent 9000 BELGIUM

Product	AURA 10 PET-CT
Model number	Model A
Basic UDI	5430002734AURA10PET/CTMV
IVDR classification	Class A – IVDR 2017/746, Rule 5, Subrule (b)
GMDN code	62011 Instrument/analyser specimen/reagent container carrier IVD
GIVD code	29.01.10.01 Other Hardware + accessories + consumables + software
EMDN code	W0299, IVD instruments – Other

We, XEOS Medical, herewith, declare under our sole responsibility that the product(s) identified in this declaration conforms to the relevant provisions of the European Regulation 2017/746 on *in vitro* Diagnostic Medical Devices. All supporting technical documentation, including the label containing the CE marking, demonstrates compliance by XEOS Medical and the AURA 10 PET-CT that is made available in Europe. The intended use of the AURA 10 PET-CT is "measuring the amount of radionuclide taken up by a particular organ or body region and generate images of the distribution of radionuclide and provide information about the anatomical localization of radionuclides by means of image reconstruction techniques."



Every precaution is taken to protect the health and safety of the patient, user and other persons. The AURA 10 PET-CT is designed according to the following legislation and standards:

- In Vitro Diagnostic Medical Devices Regulation 2017/746, RoHS Directive 2011/65/EU, Radio Equipment Directive 2014/53, Electromagnetic Compatibility Directive 2014/30/EU, Low Voltage Directive 2014/35/EU, Machinery Directive 2006/42/EC, Units of Measurement Directive 80/181/EEC.
- ISO 13485:2016, ISO 14971:2019, ISO 15223-1:2021, IEC 61010-1 (2010 + A1 2016), IEC 61010-2-091:2012, IEC 61010-2-101:2018, IEC 61326-2-6:2020, IEC 62304:2006 and IEC 62366-1:2015.

XEOS Medical keeps available for the competent national authorities the documentation allowing an understanding of the design, manufacture and performances of the AURA 10 PET-CT, so as to allow assessment of conformity with the requirements of EU Regulation 2017/746.

Gent, 17 June 2022

Name: Bjorn Delbeecke
Function: QARA Manager