PRODUCT CERTIFICATION AND DECLARATION OF CONFORMITY

Wizard2 Gamma Counter Models:

Manufacturer: PERKINELMER SINGAPORE PTE LTD
Basic UDI-DI: 081258902WIZARD2SL
Manufacturer SRN: SG-MF-000021575
Authorized Representative SRN (Emergo Europe B.V.): NL-AR-000000116

This PerkinElmer product conforms to the regulations stipulated in the CE Mark requirements for the EMC Directive (2014/30/EU), the Low Voltage Directive (2014/35/EU), In Vitro diagnostic Medical Devices Regulation (EU) 2017/746 and the RoHS 2 Directive (2011/65/EU as amended by (EU) 2015/863), in which this declaration is in conformity with the below harmonized standards.

The above models are class A devices and are self-certified. A technical file is maintained as set out in Annex II and Annex III of Regulation (EU) 2017/746

EN 55011:2009 + A1:2010 Group 1, Class A, EMC -- RF Characteristics of ISM Equipment
EN 61326-1:2013, EMC -- Requirements for Electrical Equipment for Laboratory Use
EN 61326-2-6: 2013, EMC requirements for IVD medical equipment
  EN 61000-4-2:2009, EMC -- Electrostatic Discharge Requirements
  EN 61000-4-5:2006, EMC -- Surge Immunity Requirements
  EN 61000-4-6:2009, EMC -- Conducted Disturbances (induced by RF fields) Requirements
  EN 61000-4-8:2010, EMC -- Power Frequency Magnetic Field Requirements
  EN 61000-4-11:2004, EMC -- Voltage Dips, Short Interruptions, Voltage Variations Requirements
  EN 61000-3-3:2008, EMC -- Voltage Fluctuations and Flicker
  EN 61010-1:2010, Safety Requirements for Electrical Equipment for Laboratory Use
  EN ISO 14971:2019, Medical Devices – Application of Risk Management to Medical Devices
  EN ISO 15223-1:2021, Medical Device – Symbols to be used with information to be supplied by the manufacturer – Part 1 General requirements
  EN ISO 18113:2011, In vitro diagnostic medical devices – Information supplied by the manufacturer (labeling) – Part 1 General requirements
  EN 62304:2006, Medical device software – Software life cycle processes
  EN 63000:2018, Technical Documentation for the assessment of electrical and electronic products with respect to the RoHS

This product also conforms to the Waste Electrical and Electronic Equipment Directive (WEEE, 2012/19/EU), and the Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH, EC 1907/2006).

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The intended purpose of the WIZARD2 instrument is to detect and count gamma radiation emitted from solid and liquid samples, that were prepared through the addition of a radioactive reagent for downstream clinical applications. The instrument is intended to be used by trained laboratory personnel.

The product is used for in vitro diagnostic use
The product(s) are Class A in according with the rule 5(b) set out in Annex VIII of REGULATION(EU) 2017/746

Conformity Assessment Procedure
Self-declaration, after drawing up the technical Docs set out in Annex II and III of REGULATION (EU) 2017/746.

This declaration of conformity is issued under the sole responsibility of PerkinElmer Singapore Pte Ltd.

Signed for and on behalf of: Date and Place of Issue (of this DoC)

May 12, 2022

Name: Boon Hai-Seng Singapore, Month, Date, Year
Function/Position: Principal Quality Assurance Engineer

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[EU Authorized Representative: Emergo Europe B.V., Prinsessegracht 20, 2514 AP The Hague, Netherlands]