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UK Declaration of Conformity

Product Identification		
Family Name	**Product Name & Version**	**GMDN Code**
PinPoint Test	PinPoint_Breast v1.2	61231 (Cancer risk assessment interpretive software IVD)

Manufacturer	
Name of Company	**Address**
PinPoint Data Science Ltd	C/O Nexus Discovery Way University of Leeds Leeds LS2 3AA United Kingdom

Registration Information	
Notified Body ID #	**Certificate Number**
N/A (Self-Certified Device)	N/A (Self-Certified Device)

Conformity Assessment	
Device Classification	**Route to Conformity**
General IVD	Medical Devices Regulations 2002 (SI 2002 No. 618, as modified), Annex III

Standards Applied	
EN ISO 13485:2016 + A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes
EN 13612:2002/AC:2002	Performance evaluation of in vitro diagnostic medical devices
EN ISO 14971:2019 + A11:2021	Medical devices - Application of risk management to medical devices
EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN ISO 18113-1:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements (ISO 18113-1:2009)
EN ISO 20916:2024	In vitro diagnostic medical devices – Clinical performance studies using specimens from human subjects – Good study practice
EN 62304:2006 / AC:2008	Medical device software - Software life-cycle processes
EN 62366:2015 + A1:2020	Medical devices - Application of usability engineering to medical devices

Declaration
PinPoint Data Science Ltd declares that PinPoint_Breast v1.2 is in conformity with the essential requirements and provisions of UK SI 2002 No. 618 (Medical Devices Regulations); we therefore affix a UKCA mark to this product.

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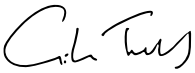
Name:	Giles Tully	Rich Savage
Title:	Chief Executive Officer	Chief Scientist
Signature:		(Approved electronically)
Date:	13 May 2026	13 May 2026