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Declaration of Conformity

Technical File Reference: TF-062, Rev Y

Issuer's Name: Hologic, Inc.
Issuer's Contact Information: 10210 Genetic Center Drive
San Diego, CA 92121 USA

Authorized Representative: Hologic BVBA
Da Vincilaan 5
1930 Zaventem
Belgium

Object of the Declaration:

Catalog No.	Description
303160	Procleix® Panther® System
PRD-05490	Procleix® Panther® System (ART, Continuous Fluid and Waste)
ASY-13105	MTU Expansion Kit (optional ART accessory)
ASY-13103	Continuous Access Kit with Assembled Waste Drawer (field upgrade kit)
ASY-13106	Waste to Drain Kit (optional ART accessory)
ASY-13472	Track Ready Shuttle Module (optional ART accessory)

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Reason: MoldSign Sig
Location: Moldova

The object of the declaration described above is in conformity with 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.

Hologic, Inc. declares that the above mentioned object of the declaration meets the provision of the Council Directive 98/79/EC for the In Vitro Diagnostic Medical Devices and the IVDD Directive 98/79/EC as transposed in the national laws of the Member States.

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

Standards Associated with the Procleix Panther System		
Standard	**Revision**	**Title**
EN ISO 13485	2016	Medical devices. Quality management systems. Requirements for regulatory purposes.
EN ISO 14971	2012	Medical devices – Application of risk management to medical devices
BS EN ISO 15223-1	2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General
BS EN ISO 18113-1	2011	In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) -– Part 1: Terms, definitions and general requirements

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Standards Associated with the Procleix Panther System		
Standard	**Revision**	**Title**
BS EN ISO 18113-3	2011	IVD medical devices: Information supplied by the manufacturer (labeling). Part 3: In vitro diagnostic instruments for professional use
BS EN 50419	2006	Marking of electrical and electronic equipment in accordance with article 11(2) of Directive 2002/96/EC (WEEE)
BS EN 60825-1	2014	Safety of laser products – Part 1: Equipment classification and requirements
BS EN 61010-2-101	2002	Safety requirements for electrical equipment for measurement, control, and laboratory use-Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment.
BS EN 62304	2006	Medical Device Software – Software life-cycle Processes
BS EN 62366 IEC 62366-1	2008 2015	Medical devices – Application of usability engineering to medical devices
BS EN 61000-3-2	2014 and 2019	Electromagnetic compatibility (EMC) - Part 3-2: Limits for harmonic current emissions (equipment input current < 16 A per phase)
BS EN 61000-3-3	2013	Electromagnetic compatibility (EMC) - Part 3. Limits, Limitation of voltage fluctuations and flicker in low voltage supply systems for equipment with rated current < 16A
BS EN 61010-2-010	2014	Safety requirements for electrical equipment for measurement, control, and laboratory use Part 2-010: Particular requirements for laboratory equipment for the heating of materials
BS EN 61010-1	2001	Safety requirements for electrical equipment for measurement, control, and laboratory use Part 1: General requirements
BS EN 60068-2-64	2008	Environmental testing – Part 2-64: Tests – Test Fh: Vibration, broadband random and guidance
BS EN 60068-2-27	2008	Environmental testing – Part 2-27: Tests – Test Ea and guidance: Shock
BS EN 61326-2-6	2013	Electrical equipment control and laboratory use – EMC requirements – particular requirements – In vitro diagnostic (IVD) medical equipment.
BS EN 61010-2-081	2001 +A1:2003	Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use, Part 2-081: Particular Requirements for Automatic and Semi-Automatic Laboratory Equipment for Analysis and Other Purposes: First Edition

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Additional Information:

Classification/Conformity Assessment:	Self-Certified, Annex III
Date of Initial CE Mark:	September 2010
Signed for and on behalf of:	Hologic, Inc. San Diego, CA 92121 USA

Jeff Zinza 10/23/2019

Jeff Zinza, Sr. Director, Regulatory Affairs **Date**