Declaration of Conformity

Technical File Reference:	TF-078, Rev M
Manufacturer's Name:	Hologic Inc.
Manufacturer's Contact Information:	10210 Genetic Center Drive San Diego, CA 92121 USA
Additional Manufacturing Facilities:	Hologic, Ltd. Oaks Business Park Crewe Road Wythenshawe, Manchester M23 9HZ United Kingdom
Authorized Representative:	Hologic BV Da Vincilaan 5 1930 Zaventem Belgium

Object of the Declaration:

Catalog No.	Description	Kit Size
PRD-03003	Aptima Specimen Diluent	4 x 30 mL
PRD-06783	Aptima Whole Blood Diluent Tubes	100 each

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:

Standard	Revision	Title
BS EN ISO 18113-1 BS EN ISO 18113-2	2011	In vitro diagnostic medical devices – Information supplied by the manufacturer (labeling) Part 1: Terms, definitions and general requirements. Part 2: IVD Reagents for Professional Use
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 requirements
EN ISO 13485	2016	Medical devices-Quality management systems-Requirements for regulatory purposes
BS EN 13612	2002	Performance evaluation of in vitro diagnostic medical devices
BS EN ISO 23640	2015	In vitro diagnostic medical devices – Evaluation of stability of in vitro diagnostic reagents
BS EN 13975	2003	Sampling procedures used for acceptance testing of in vitro diagnostic medical devices – Statistical aspects
EN ISO 14971	2019	Medical devices-Application of risk management to medical devices –Rationale for requirements

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Additional Information:

Classification / Conformity Assessment:	Self–Certified, Annex III
Date of Initial CE Mark :	November 2014
Signed for and on behalf of:	Hologic, Inc. San Diego, CA 92121 USA

04-JUN-2021

Jeffrey Hergesheimer, Sr. Manager, Regulatory Affairs — Date