GRIFOLS

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Date: 2023.10.20 16:33:44 EEST
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Declaration of Conformity

Technical File Reference: DD-010

Issuer's Name:
Issuer's Contact Information:
Grifols Diagnostic Solutions Inc.
4560 Horton Street
Emeryville, CA 94608, USA

Authorized Representative:
Diagnostic Grifols, S.A.
Passeig Fluvial, 24
08150 Parets del Vallès, Spain

Object of the Declaration:

Catalog No.	Description
303330 / 303715	Procleix® Ultrio Elite® Assay
303334	Procleix® Ultrio Elite® HIV, HCV, and HBV Discriminatory Probe Reagents
303331 / 303722	Procleix® Ultrio Elite® Target Enhancer Reagent
303333	Procleix® Ultrio Elite® Negative Calibrators
303332	Procleix® Ultrio Elite® Positive Calibrators
303719 / 303723	Procleix® Ultrio Elite® Assay Calibrators Kit

Grifols Diagnostic Solutions 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
EN ISO 13485	2016	Medical devices. Quality management systems. Requirements for regulatory purposes.
EN 13612	2002	Performance evaluation of *in-vitro* diagnostic medical devices
EN 13975	2003	Sampling procedures used for acceptance testing of *in vitro* diagnostic medical devices – Statistical aspects
EN ISO 14971	2012	Medical devices – Application of risk management to medical devices – Rationale for requirements
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 18113-1 EN ISO 18113-2	2011	*In Vitro* Diagnostic Medical Devices – Information Supplied by the Manufacturer. Part 1: Terms, definitions and general requirements. (Part 2: IVD Reagents for Professional Use)
ISO 23640	2015	*In Vitro* diagnostic medical devices – Evaluation of stability of *in vitro* diagnostic reagents

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Additional Information:

Classification/ Conformity Assessment:	Annex II, List A/ Annex IV, Section 4
Notified Body:	Polish Centre for Testing and Certification (PCBC) (1434)
Certificate Number:	1434-IVDD-222/2019
Date of Current CE Mark:	26 April 2019

Signed for and on behalf of: Grifols Diagnostic Solutions Inc.

26 Apr 2019

Amanda Doe, Manager, Regulatory Affairs **Date**