GRIFOLS

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Declaration of Conformity

Technical File Reference: SDTF-002, Rev. 002

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
301120	Procleix® Auto Detect Reagents Kit (Procleix® and Procleix® Tigris Systems)
303345	Procleix® Auto Detect Reagents Kit (Procleix® Panther System)

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 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 and 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:	Self-Certified, Annex III
Date of Initial CE mark:	March 29, 2004
Date of Current CE Mark:	May 15, 2019

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

15 May 2019

Amanda Doe, Manager Regulatory Affairs **Date**