GRIFOLS

Declaration of Conformity

Technical File Reference: SDTF-003, Rev. 001

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
301046E-01	Procleix SysCheck 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	2012	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 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:	Self-Certified, Annex III
Notified Body:	Underwriters Laboratories International (UK) Ltd (0843)
Date of Initial CE Mark:	March 2003
Date of Current CE Mark:	January 2018

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

Diane C. Day 8 January 2018

Diane C. Day, Vice President, Regulatory Affairs **Date**