GRIFOLS

Declaration of Conformity

Technical File Reference: SDTF-001, 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
302441	Procleix® Oil Kit (Procleix® and Procleix® Tigris Systems)
303665	Procleix® Wash Solution Kit (Procleix® and Procleix® Tigris Systems)
303666	Procleix® Buffer for Deactivation Fluid Kit (Procleix® and Procleix® Tigris Systems)
303344	Procleix® Assay Fluids Kit (Procleix® Panther® System)

Grifols Diagnostic Solution, 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 18113-1 and 2:2011	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
EN ISO 15223-1	2016	Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements
EN ISO 13485	2016	Medical devices-Quality management systems-Requirements for regulatory purposes
ISO 23640	2015	*In vitro* diagnostic medical devices- Evaluation of stability of *in vitro* diagnostic reagents
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

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Date: 2022.11.09 16:48:31 EET
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Location: Moldova

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Additional Information:

Classification/ Conformity Assessment:	Self-Certified, Annex III
Date of Initial CE Mark:	February 03, 2009
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**