

# GRIFOLS

## Declaration of Conformity

**Technical File Reference:** SDTF-002, Rev. 002

**Issuer's Name:** Grifols Diagnostic Solutions Inc.  
**Issuer's Contact Information:** 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 <sup>®</sup> Auto Detect Reagents Kit (Procleix <sup>®</sup> and Procleix <sup>®</sup> Tigris Systems)
303345	Procleix <sup>®</sup> Auto Detect Reagents Kit (Procleix <sup>®</sup> 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 <i>in vitro</i> 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	<i>In Vitro</i> 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	<i>In vitro</i> diagnostic medical devices- Evaluation of stability of <i>in vitro</i> 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

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**Amanda Doe, Manager Regulatory Affairs**

**Date**