GRIFOLS

Declaration of Conformity

Technical File Reference: SDTF-010, Rev. 001

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
740817	Procleix Reagent Preparation Incubator (RPI) – 220-240 volt
740820	Procleix Reagent Preparation Incubator 250 (RPI250) – 220-240 volt

The object of declaration described above is in conformity with Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

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
ISO 13485	2003	Medical devices - Quality management systems – Requirements for regulatory purposes
EN ISO 14971	2012	Medical devices – Application of risk management to medical devices
EN ISO 15223-1	2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General
EN ISO 18113-1	2011	In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) -– Part 1: Terms, definitions and general requirements
EN ISO 18113-3	2011	IVD medical devices: Information supplied by the manufacturer (labeling). Part 3: In vitro diagnostic instruments for professional use
EN 50419	2006	Marking of electrical and electronic equipment in accordance with article 11(2) of Directive 2002/96/EC (WEEE)
EN 61326-1	2006	Electrical equipment for measurement, control and laboratory use – EMC requirements Part 1: General requirements

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Date: 2023.10.20 16:33:17 EEST
Reason: MoldSign Signature
Location: Moldova

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EN 61000-3-2	2006+A1:2009+ A2:2009/ 4-7:2008	Electromagnetic compatibility (EMC) - Part 3-2: Limits for harmonic current emissions (equipment input current < 16 A per phase)
EN 61000-3-3	2008 Annex B2	Electromagnetic compatibility (EMC) - Part 3. Limits, Limitation of voltage fluctuations and flicker in low voltage supply systems for equipment with rated current < 16A
IEC 61010-1	2001	Safety requirements for electrical equipment for measurement, control, and laboratory use. Part I: General requirements
IEC 61010-2-010	2003	Safety requirements for electrical equipment for measurement, control, and laboratory use. Part II: Particular requirements for laboratory equipment for the heating of materials

Additional Information:

Classification/
Conformity Assessment: Self-Certified, Annex III
Notified Body: Underwriters Laboratories International (UK) Ltd (0843)
Date of Initial CE Mark (RPI): October 2004
Date of Initial CE Mark (RPI250): September 2010
Date of Current CE Mark (RPI/RPI250): October 2018

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

01/31/2019

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