GRIFOLS

Grifols Diagnostic Solutions Inc.
4560 Horton Street
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USA

DECLARATION ON RATIONALE FOR NO GENERAL IVD EC CERTIFICATES
Procleix Assay Fluids / Procleix Auto Detect / Procleix Panther System / Procleix RPI 250

Wednesday, 4th January 2022

To Whom It May Concern:

We, Grifols Diagnostic Solutions, Inv., with business address at 4560 Horton Street, Emeryville, CA 94608, USA, hereby declare that Procleix Assay Fluids / Procleix Auto Detect / Procleix Panther System / Procleix Reagent Preparation Incubator (RPI) 250, are classified as self-certified / Annex III In-Vitro Diagnostic Devices (IVD), based on the EU IVDD 98/79/EC. As such, there is NO EC Certificates available or necessary for these class of products.

Article 9 of IVDD 98/79/EC prescribes the conformity assessment procedures for CE marking. One fundamental difference of the procedure is whether an EU notified body (NB) is involved. While all Annex II devices need NB's evaluation, Annex III devices are Self-Certified, i.e. there is no involvement of a NB.

The Procleix Ultrio Elite Assay is classified as Annex II, List A and the conformity assessment procedure is Annex IV – Full Quality Assurance route. Therefore, two EC Certificates are issued for the product: EC Certificate --- Full Quality Assurance System approval certificate, and an EC Design Examination Certificate. Conversely, the conformity assessment for Procleix Assay Fluids / Procleix Auto Detect / Procleix Panther System / Procleix Reagent Preparation Incubator (RPI) 250 is Annex III, which does not require NB's evaluation. As such, there is no EC certificates for these products.

Acknowledgement

GRIFOLS DIAGNOSTIC SOLUTIONS INC.

Signed by: _____
Name: PHILIPP NOVALES-LI, DMedSc, PhD, DPhil (Oxford)
Title: Director, Global Regulatory Affairs
Date: 05 January 2022

GRIFOLS GRIFOLS GLOBAL REGULATORY AFFAIRS DIAGNOSTIC SOLUTIONS INC.

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