



EU DECLARATION OF CONFORMITY

Manufacturer: Grifols Diagnostic Solutions Inc.
10808 Willow Court
San Diego, CA 92127
SRN: US-MF-000004304

EU Authorised Representative: Diagnostic Grifols
Passeig Fluvial, 24
Parets del Vallès, Spain 08150
SRN: ES-AR-000001573

Product Trade Name / Catalogue Number: Procleix Assay Fluids Kit / 303344

Affected Product(s):

Catalogue Number	Name	Intended Purpose	Basic UDI-DI
303344	Procleix Assay Fluids Kit (Procleix Oil, Procleix Wash Solution and Procleix Buffer for Deactivation Fluid)	The Procleix Assay Fluids Reagents are to be used with Procleix Assays that are run on the Procleix Panther System.	0859882007Procleix011ZD

Classification: Class A according to Rule 5 of Annex VIII of EU 2017/746
Conformity Assessment Route: Annexes II and III of EU 2017/746
Certificates issued by the Notified Body: NA

GRIFOLS DIAGNOSTIC SOLUTIONS DECLARES, UNDER SOLE RESPONSIBILITY, THAT THE ABOVE-MENTIONED PRODUCT IS IN CONFORMITY WITH THE REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 5 APRIL 2017 ON IN VITRO DIAGNOSTIC MEDICAL DEVICES. ALL SUPPORTING DOCUMENTATION IS AVAILABLE UNDER THE PREMISES OF THE MANUFACTURER.

First issue date under IVDR:

24 MAY 2022

Place, Date of Issue:

San Diego, California, USA, 01 August 2025

Signature:



A handwritten signature in black ink, appearing to read "Sumit Khurana", written over a horizontal line.

Sumit Khurana

Quality, Regulatory Compliance and Technical Director

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