Grifols Diagnostic Solutions Inc.
10808 Willow Court
San Diego, CA.92127
USA

GRIFOLS

CE

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 Auto Detects Reagents Kit / 303345 / 9053575

Affected Product(s):

Catalogue Number	Name	Intended Purpose	Basic UDI-DI
303345	Procleix Auto Detect Reagent Kit 1,000 test kit	The Procleix Auto Detect Reagents are to be used with Procleix Assays that are run on the Procleix Panther System.	0859882007Procleix012ZF
9053575	Procleix Auto Detect Reagent Kit 4,000 test kit		

Classification: Class A according to Rule 5(a) of Annex VIII of EU 2017/746

Conformity Assessment Route: Annexes II and III from IVD Regulation 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.

Digitally signed by Ceaicovschi Tudor
Date: 2025.10.07 08:21:37 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

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First issue date under IVDR: 24 MAY 2022

Place, Date of Issue: San Diego, California, USA, 01 August 2025

Signature:

Sumit Khurana

Quality, Regulatory Compliance and Technical Director

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