GRIFOLS

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

CE 0123

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: Procleix Ultrio Elite Assay

Affected Product(s):

Catalogue Number	Name	Intended Purpose	Basic UDI-DI
303330 303715	Procleix Ultrio Elite Assay Kits	The Procleix Ultrio Elite Assay is a qualitative *in vitro* nucleic acid amplification test for the detection of human immunodeficiency virus type 1 and human immunodeficiency virus type 2 (HIV) RNA, hepatitis C virus (HCV) RNA, and/or hepatitis B virus (HBV) DNA in plasma and serum specimens from human donors, tested individually or in pools. It is also intended for use in testing plasma and serum to screen organ and tissue donors, including cadaveric (nonheart-beating) donors. It is not intended for use on samples of cord blood. The Procleix Ultrio Elite Assay is intended for use on the fully automated Procleix Panther System. The Procleix Ultrio Elite Assay is intended for use by qualified clinical laboratory personnel specifically instructed and trained in the operation of the Procleix Panther System and *in vitro* diagnostic procedures.	0859882007Procleix001ZA
303334	Procleix Ultrio Elite Assay HIV, HCV, and HBV Discriminatory Probe Reagents		
303331 303722	Procleix Ultrio Elite Assay Target Enhancer Reagent		
303719 303723	Procleix Ultrio Elite Assay Calibrators Kit		
303333	Procleix Ultrio Elite Assay Negative Calibrators		
303332	Procleix Ultrio Elite Assay Positive Calibrators		

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		This is a first-line assay and not intended for use as an aid in diagnosis or as a confirmatory test.	

Classification: Class D according to Rule 1 of Annex VIII of EU 2017/746

Conformity Assessment Route: Annex IX of EU 2017/746

Notified Body: TÜV SÜD Product Service GmbH, number 0123

Certificates issued by the Notified Body: Procleix Ultrio Elite Assay: IVDR No. V76 119490 0008 Rev. 00

EU Quality Management System Certificate no: V13 119490 0011 Rev. 00

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.

The object of the declaration described above is in conformity with the requirements of the following common specifications (CS): Common specifications for in vitro-diagnostic medical devices laid down in Commission Implementing Regulation (EU) 2022/1107.

First issue date under IVDR: 14 DEC 2023

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

Signature:

GRIFOLS
QUALITY AND REGULATORY COMPLIANCE
GRIFOLS DIAGNOSTIC SOLUTIONS INC. (USA)

Sumit Khurana

Quality, Regulatory Compliance and Technical Director

Signed for and on behalf of Grifols Diagnostic Solutions Inc.