ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-IVDR-099

Product Service

EU Technical Documentation Assessment Certificate (IVDR)

Pursuant to Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices, Annex IX, Chapter II

No. V76 119490 0008 Rev. 00

Manufacturer:

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

SRN Manufacturer - US-MF-000004304

Authorized Representative:

Diagnostic Grifols, S.A.
Passeig Fluvial 24, 08150 Parets del Vallès (Barcelona), SPAIN

The technical documentation has been evaluated in accordance with Regulation (EU) 2017/746, Annex IX Chapter II with a positive result.

Details on devices covered by the technical documentation are described on the following page(s). The report referenced below summarises the results of the assessment and includes reference to relevant CS, harmonised standards and test reports.

If class B or C self-/near-patient testing are covered by this certificate, the assessment was conducted according to section 4 and 5.1. An EU Quality Management System Certificate in accordance with Annex IX Chapter I is required before placing them on the market.
If class C companion diagnostics devices are covered by this certificate, the assessment was conducted according to section 4 and 5.2. An EU Quality Management System Certificate in accordance with Annex IX Chapter I is required before placing them on the market.
If class D devices are covered by this certificate, verification of batches of manufactured devices according to Annex IX Sections 4.12 and 4.13 is applicable. An EU Quality Management System Certificate in accordance with Annex IX Chapter I is required before placing them on the market.

All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:V76 119490 0008 Rev. 00

Report No.: 713376197
Preceding Certificate No.: V70 088332 0015 Rev. 00

Valid from: 2025-07-28
Valid until: 2028-12-13

Issue date: 2025-07-28

Marta Carnielli
Head of Certification IVD

Digitally signed by Ceaicovschi Tudor
Date: 2025.10.07 08:19:36 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

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Classification: Class D

Basic UDI-DI: 0859882007Procleix001ZA

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

Device Group: IVR 0502 - Devices intended to be used to detect the presence of, or exposure to transmissible agents in blood, blood components, cells, tissues or organs, or in any of their derivatives, to assess their suitability for transfusion, transplantation or cell administration

Device(s):

Procleix Ultrio Elite Assay
Ref. No.: 303330, 303715
Consisting of the following components:

Procleix Ultrio Elite Assay Target Enhancer Reagent
Ref. No.: 303331, 303722

Procleix Ultrio Elite Assay HIV, HCV, and HBV Discriminatory Probe Reagents
Ref. No.: 303334

Procleix Ultrio Elite Assay Calibrators
Ref. No.: 303719, 303723

Procleix Ultrio Elite Assay Negative Calibrators
Ref. No.: 303333

Procleix Ultrio Elite Assay Positive Calibrators
Ref. No.: 303332

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The validity of this certificate depends on conditions and/or is limited to the following: -none-

Revision History:

Rev.	Dated	Report	Description
00	2025-07-28	713376197	Amended: Change of certificate holder's data Administrative merge / transfer to new Certificate Type

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