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 Quality Management System Certificate

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

Certificate No. V13 119490 0011 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 quality management system has been evaluated in accordance with Regulation (EU) 2017/746, Annex IX Chapter I with a positive result.

Details on devices covered by the quality management system 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.
The certified quality management system is subject to periodical surveillance.

If class A devices in sterile conditions are covered by this certificate, the audit was limited to the aspects relating to establishing, securing, and maintaining sterile conditions.
If class B or C excluding self-/near-patient-testing, or class C companion diagnostics devices are covered by this certificate, the quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis. The periodical surveillance includes further assessment of the technical documentation on the basis of representative samples.
If class D devices, class B or C self-/near-patient testing, or class C companion diagnostics devices are covered by this certificate, an EU Technical Documentation Assessment Certificate in accordance with Annex IX Chapter II 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:V13 119490 0011 Rev. 00

Report No.: 713376197
Preceding Certificate No.: V10 088332 0016 Rev. 01

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

Marta Carnielli
Head of Certification IVD

Issue date: 2025-07-28

Digitally signed by Ceaicovschi Tudor
Date: 2025.10.07 08:19:46 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

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Certificate No. V13 119490 0011 Rev. 00

Classification:	Class D
Device Group:	IVR 0502 - Infectious diseases: Blood transfusion, transplantation or cell administration
Intended Purpose:	See product certificate
The validity of this certificate depends on conditions and/or is limited to the following:	-none-

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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