GRIFOLS

Diagnostic Grifols, S.A.
Passeig Fluvial, 24
08150 Parets del Vallès
Barcelona - ESPAÑA
Tel. [34] 935 710 400
Fax [34] 935 731 132
diagnostic@grifols.com

Declaración CE de Conformidad

EC Declaration of Conformity

Fabricante:
Manufacturer:

DIAGNOSTIC GRIFOLS, S.A.
Passeig Fluvial, 24
08150 - Parets del Vallès
Barcelona. ESPAÑA

Familia de productos:
Product family:

Tarjetas DG Gel / *DG Gel Cards*

Clasificación de acuerdo con la Directiva 98/79/CE:
Classification according to Directive 98/79/EC:

Anexo II Lista A / *Annex II List A*

Producto y referencia:
Product and reference:

DG Gel AB (x4)	210324 / 210346	DG Gel Rh Pheno	210327 / 210349
DG Gel ABO-CDE	210313 / 210340	DG Gel Rh Pheno+Kell	210328 / 210350
DG Gel ABO/Rh	210310 / 210355	DG Gel T/S Poly	210334 / 210377
DG Gel ABO/Rh (2D)	210311 / 210338	DG Gel Confirm P	210335 / 210351
DG Gel Anti-D	210314 / 210341	DG Gel ABO/Rh+Kell (RT)	210336 / 210352
DG Gel Confirm	210312 / 210339	DG Gel Newborn	210337 / 210353
DG Gel CT	210318 / 210374	DG Gel ABO/Rh (CR)	210380 / 210378
DG Gel ABO/Rh+Kell	210325 / 210347	DG Gel Double Pheno	210381 / 210382
DG Gel ABO/Rh (2D)+Kell	210326 / 210348		

Ruta de evaluación de la conformidad:
Conformity assessment route:

Anexo IV Directiva 98/79/CE
Annex IV Directive 98/79/EC

DIAGNOSTIC GRIFOLS, S.A. declara bajo su propia responsabilidad que los productos indicados anteriormente cumplen los requisitos esenciales de la Directiva sobre Productos Sanitarios para Diagnóstico In Vitro 98/79/CE. Esta Declaración está basada en los certificados nº 2003100380CT de 30 de mayo de 2012, nº 2003100381ED, nº 2008070549 /0550 /554 /0555ED y nº 2008100572 /0573 /0574 /0575 /0576 /0577ED de 13 de octubre de 2008, nº 2009030598 /0599 /0600 /0601ED de 09 de marzo de 2009, nº 201103761ED de 21 de marzo de 2011 y nº 2011090770ED de 31 de agosto de 2011 emitidos por el Organismo Notificado nº 0318.

DIAGNOSTIC GRIFOLS, S.A. declares under sole responsibility that the products specified above comply with the essential requirements of the Directive on In Vitro Diagnostic Medical Devices 98/79/CE. This Declaration is supported by certificates nº 2003100380CT dated on May 30, 2012, nº 2003100381ED, nº 2008070549 /0550 /0554 /0555ED and nº 2008100572 /0573 /0574 /0575 /0576 /0577ED dated on October 13, 2008, nº 2009030598 /0599 /0600 /0601ED dated on March 09, 2009, nº 201103761ED dated on March 21, 2011 and nº 2011090770ED dated on August 31, 2011 issued by Notified Body no.0318.

CE 0318

Parets del Vallès, 26 de junio de 2012
Parets del Vallès, June 26th of 2012

Oriol Duñach Fulla
Director General
General Manager

Joaquín Alberto Tamparillas
Director Técnico
Technical Director

Vertimas iš anglų kalbos

/logotipas/ /rekvizitai/

CE ATITIKTIES DEKLARACIJA

Gamintojas: DIAGNOSTIC GRIFOLS, S.A.
Passeig Fluvial, 24
08150 – Parets del Valles
Barselona, ISPANIJA

Produktų šeima: DG Gel Cards

Klasifikacija pagal direktyvą 98/79/CE: II priedo A sąrašas

Produktas ir jo kodas:

DG Gel AB (x4)	210324 / 210346	DG Gel Rh Pheno	210327 / 210349
DG Gel ABO-CDE	210313 / 210340	DG Gel Rh Pheno+Kell	210328 / 210350
DG Gel ABO/Rh	210310 / 210355	DG Gel T/S Poly	210334 / 210377
DG Gel ABO/Rh (2D)	210311 / 210338	DG Gel Confirm P	210335 / 210351
DG Gel Anti-D	210314 / 210341	DG Gel ABO/Rh+Kell (RT)	210336 / 210352
DG Gel Confirm	210312 / 210339	DG Gel Newborn	210337 / 210353
DG Gel CT	210318 / 210374	DG Gel ABO/Rh (CR)	210380 / 210378
DG Gel ABO/Rh+Kell	210325 / 210347	DG Gel Double Pheno	210381 / 210382
DG Gel ABO/Rh (2D)+Kell	210326 / 210348		

Atitikties įvertinimo kelias: 98/79/EC direktyvos IV priedas

DIAGNOSTIC GRIFOLS, S.A., prisiimdama visą atsakomybę, tvirtina, jog aukščiau minimas produktas atitinka pagrindinius reikalavimus, pateikiamus In vitro diagnostinių medicinos priemonių direktyvoje 98/79/EC. Ši deklaracija yra paremta sertifikatu nr. 2003100380CT, išleistu 2013 m. gegužės 30 d., nr. 2003100381ED, nr. 2008070549/0550/0554/0555ED ir nr. 2008100572/0573/0574/0575/0576/0577ED, išleistu 2008 m. spalio 13 d., nr. 2009030598/0599/0600/0601ED, išleistu 2009 m. kovo 9 d., nr. 201103761ED, išleistu 2011 m. kovo 21 d. ir nr. 2011090770ED, išleistu 2011 m. rugpjūčio 31 d. notifikuotosios įstaigos nr. 0318.

/CE0318 žyma/

Parets del Valles, 2012 m. gegužės 26 d.

/parašas/
Oriol Dunach Fulla
Generalinis direktorius

/parašas/
Joaquin Alberto Tamparillas
Techninis direktorius

/logotipas/

Tikslus dokum
Vertėjas (-a)
Data:
UAB Diamedi
Molėtų pl. 73,
Lietuva
Tel. 8 5 279 0080

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EU DECLARATION OF CONFORMITY

Manufacturer:

DIAGNOSTIC GRIFOLS, S.A.
Passeig Fluvial, 24
08150 – Parets del Vallès (Barcelona)
Spain
SRN: ES-MF-000000784

Affected Product(s):

Catalogue Number	Name	Intended Purpose	Basic UDI-DI
210354	DG Gel Sol	DG Gel Sol is a reagent for preparing red blood cell suspensions and plasma/serum dilutions used with DG Gel cards.	843658373GELSOLPA

Classification: Class A devices according to Rule 5 of Annex VIII of the IVDR EU 2017/746.

DIAGNOSTIC GRIFOLS, S.A. DECLARES, UNDER SOLE RESPONSIBILITY, THAT THE ABOVE-MENTIONED PRODUCT ARE 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 emission date under IVDR: March 7th, 2022

Place, Date of Issue: Parets del Vallès, April 9th, 2024

Signature:

Marta Genís Lumbreras
Technical Director
Diagnostic Grifols, S.A.

IVDR_DoC_DGGelSol_Rev.001

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Bonnstrasse 9
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www.grifols.com

ES ATITIKTIES DEKLARACIJA

Gamintojas:

DIAGNOSTIC GRIFOLS, S.A.
Passeig Fluvial, 24
08150 — Parets del Valles (Barcelona)
Ispanija
SRN: ES-MF-000000784

Produktas (-ai):

Katalogo numeris	Pavadinimas	Numatytoji paskirtis	Bazinis UDI-DI
210354	DG Gel Sol	DG Gel Sol yra reagentas eritrocitų suspensijų paruošimui ir plazmos ir (ar) serumo praskiedimams, naudojant DG Gel korteles.	843658373GELSOLPA

Klasifikacija: A klasės prietaisai pagal IVDR ES 2017/746 VIII priedo 5 taisyklę.

DIAGNOSTIC GRIFOLS, S.A. PAREIŠKIA, KAD PIRMIAU MINĖTAS PRODUKTAS ATITINKA 2017 M. BALANDŽIO 5 D. EUROPOS PARLAMENTO IR TARYBOS REGLAMENTĄ (ES) 2017/746 DĖL IN VITRO DIAGNOSTIKOS MEDICINOS PRIETAISŲ. VISI PATVIRTINAMIEJI DOKUMENTAI YRA SAUGOMI GAMINTOJO.

Pirmojo išleidimo data pagal IVDR: 2022 m. gegužės 7 d.

Išleidimo vieta, data: Parets del Valles, 2024 m. balandžio 9 d.

Parašas:

/parašas/ /spaudas/

Marta Genis Lumbreras
Techninės srities direktorius
Diagnostic Grifols, S.A.

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 (Class D Devices)

No. V70 059075 0080 Rev. 00

Manufacturer:

Medion Grifols Diagnostics AG
Bonnstrasse 9
3186 Düdingen
SWITZERLAND

SRN Manufacturer - CH-MF-000024272

Authorized Representative:

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

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has drawn up and presented a Technical Documentation according to Annex II and III of the Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices. Details on devices covered by the Technical Documentation are described on the following page(s).
The Report referenced below summarizes the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX, Chapter II, of this regulation with a positive result. In order to maintain this certificate, the manufacturer shall submit Periodic Safety Update Reports at least annually to the notified body TÜV SÜD Product Service GmbH. Verification of manufactured class D devices according to Annex IX Sections 4.12 and 4.13 is applicable. In order to place the devices on the market with CE-marking, an EU Quality Management System Certificate pursuant to Annex IX Chapters I and III is necessary in addition to this EU Technical Documentation Assessment Certificate. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:V70 059075 0080 Rev. 00

Report No.:	713281763
Valid from:	2023-10-04
Valid until:	2028-10-03

Issue date: 2023-10-04

Marta Carnielli
Head of Notified Body IVD

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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BS-IVDR-099

TÜV SÜD Product Service

EU Technical Documentation Assessment Certificate (IVDR)

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

No. V70 059075 0080 Rev. 00

Classification: Class D
Device Group: W0103030402 - CONTROL KITS (IMMUNOHAEMATOLOGY)
Basic UDI-DI: 764013734Control-002VZ

Intended Purpose: Extended IV Control is intended to allow for regular control of materials, work procedures and instrument procedures through a qualitative test method for: (i) the determination of the ABO, Rhesus and K antigens; (ii) the determination of the appropriate ABO blood group antibodies; (iii) the detection of unexpected antibodies in both antiglobulin and enzyme technique; and (iv) ABO compatibility testing.
For use with the DG Gel System, in the manual method or with automated instruments, and tube test.

Device(s): Extended IV Control - product code 213286

Classification: Class D
Device Group: W0103030402 - CONTROL KITS (IMMUNOHAEMATOLOGY)
Basic UDI-DI: 764013734Control-003W3

Intended Purpose: Essential II Control is intended to allow for regular control of materials, work procedures and instrument procedures through a qualitative test method for: (i) the determination of the ABO, Rhesus and K antigens; (ii) the determination of the appropriate ABO blood group antibodies; and (iii) the detection of unexpected antibodies in both antiglobulin and enzyme technique.
For use with the DG Gel System, in the manual method or with automated instruments, and tube test.

Device(s): Essential II Control - product code 213287

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

Revision History:

Rev.	Dated	Report	Description
00	2023-10-04	713281763	Initial issuance

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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

ES techninės dokumentacijos vertinimo sertifikatas (IVDR)

Pagal Reglamento (ES) 2017/746 dėl *in vitro* diagnostikos medicinos prietaisų IX priedo II skyrių (D klasės prietaisai)

Nr. V70 059075 0080, Red. 00

Gamintojas:

Medion Grifols Diagnostics AG
Bonnstrasse 9
3186 Düdingen
ŠVEICARIJA

SRN gamintojas - CH-MF-000024272

Įgaliotas atstovas:

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

TÜV SÜD Product Service GmbH sertifikavimo įstaiga patvirtina, kad gamintojas parengė ir pateikė techninę dokumentaciją pagal Reglamento (ES) 2017/746 dėl in vitro diagnostikos medicinos prietaisų II ir III priedus. Išsami informacija apie prietaisus, kuriems skirta techninė dokumentacija, aprašyta tolesniame (-iuose) puslapyje (-iuose).
Toliau nurodytoje ataskaitoje apibendrinami vertinimo rezultatai ir pateikiamos nuorodos į atitinkamas CS, suderintuosius standartus ir testavimo ataskaitas. Atitikties vertinimas atliktas pagal šio reglamento IX priedo II skyriaus nuostatas ir jo rezultatas yra teigiamas. Siekdamas išlaikyti šį sertifikatą, gamintojas ne rečiau kaip kartą per metus notifikuotajai įstaigai TÜV SÜD Product Service GmbH pateikia periodiškai atnaujinamas saugos ataskaitas. Taikomas pagamintų D klasės prietaisų tikrinimas pagal IX priedo 4.12 ir 4.13 skirsnius. Norint pateikti prietaisus rinkai su CE ženklinimu, be šio ES techninių dokumentų įvertinimo sertifikato, būtina turėti ES kokybės valdymo sistemos sertifikatą pagal IX priedo I ir III skyrius. Išsamią informaciją ir sertifikato galiojimą rasite apsilankę adresu www.tuvsud.com/ps-cert?q=cert:V70 059075 0080 Rev. 00

Ataskaitos nr.:	713281763
Galioja nuo:	2023-10-04
Galioja iki:	2028-10-03

/parašas/
Marta Carnielli
Notifikuotosios įstaigos vadovas, IVD

Išleidimo data: 2023-10-04

TÜV SÜD Product Service GmbH yra notifikuotoji įstaiga, kurios identifikacinis nr. 0123.
TÜV SÜD Product Service GmbH • Sertifikavimo įstaiga • Ridlerstraße 65 • 80339 Munich • Vokietija

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TÜV SÜD
Product Service

ES techninės dokumentacijos vertinimo sertifikatas (IVDR)

Pagal Reglamento (ES) 2017/746 dėl *in vitro* diagnostikos medicinos prietaisų IX priedo II skyrių (D klasės prietaisai)

Nr. V70 059075 0080, red. 00

Klasifikacija:	D klasė
Prietaisų grupė:	W0103030402 - CONTROL KITS (IMMUNOHAEMATOLOGY)
Bazinis UDI-DI:	764013734Control-002VZ
Numatytoji paskirtis:	„Extended IV Control“ kontrolinė medžiaga skirta reguliariai kontroliuoti medžiagas, darbo procedūras ir prietaisų procedūras, taikant kokybinį tyrimo metodą, skirtą: (i) ABO, rezus ir K antigenų nustatymui; (ii) atitinkamų ABO kraujo grupių antikūnų nustatymui; (iii) netikėtų antikūnų nustatymui tiek antiglobulino, tiek fermentiniu metodu; (iv) ABO suderinamumo tyrimui. Skirta naudoti su DG gelio sistema, taikant rankinį metodą arba automatinius prietaisus, ir atliekant tyrimus mėgintuvėliuose.
Prietaisas (-ai):	Extended IV Control – produkto kodas 213286.
Klasifikacija:	D klasė
Prietaisų grupė:	W0103030402 - CONTROL KITS (IMMUNOHAEMATOLOGY)
Bazinis UDI-DI:	764013734Control-003W3
Numatytoji paskirtis:	„Essential II Control“ kontrolinė medžiaga skirta reguliariai kontroliuoti medžiagas, darbo procedūras ir prietaisų procedūras, taikant kokybinį tyrimo metodą, skirtą: (i) ABO, rezus ir K antigenų nustatymui; (ii) atitinkamų ABO kraujo grupių antikūnų nustatymui; (iii) netikėtų antikūnų nustatymui tiek antiglobulino, tiek fermentiniu metodu. Skirta naudoti su DG gelio sistema, taikant rankinį metodą arba automatinius prietaisus, ir atliekant tyrimus mėgintuvėliuose.
Prietaisas (-ai):	Essential II Control - produkto kodas 213287
Šio sertifikato galiojimas priklauso nuo sąlygų ir (arba) apsiriboja šiomis sąlygomis:	-nėra-

Pakeitimų istorija:

Red.	Data	Ataskaita	Aprašymas
00	2023-10-04	713281763	Pirminis leidimas

Diagnostic Grifols, S.A.
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diagnostic@grifols.com

EU DECLARATION OF CONFORMITY

Manufacturer:

DIAGNOSTIC GRIFOLS, S.A.
Passeig Fluvial, 24
08150 – Parets del Vallès (Barcelona)
Spain
SRN: ES-MF-000000784

Affected Product(s):

Catalogue Number	Name	Intended Purpose	Basic UDI-DI
213679	DG Fluid A	DG Fluid A and DG Fluid B are used for the washing of the Grifols analyzers' fluidic system. The solutions must be diluted prior to use.	843658373FLUIDLZ
213678	DG Fluid B		

Classification: Class A devices according to Rule 5 of Annex VIII of the IVDR EU 2017/746.

DIAGNOSTIC GRIFOLS, S.A. DECLARES, UNDER SOLE RESPONSIBILITY, THAT THE ABOVE-MENTIONED PRODUCT ARE 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 emission date under IVDR: February 15th, 2022

Place, Date of Issue: Parets del Vallès, April 9th, 2024

Signature:

GRIFOLS
Diagnostic Grifols, S.A.

Marta Genís Lumbreras
Technical Director
Diagnostic Grifols, S.A.

Medion Grifols Diagnostics, S.A.
Passeig Fluvial, 24
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ES ATITIKTIES DEKLARACIJA

Gamintojas:

DIAGNOSTIC GRIFOLS, S.A.
Passeig Fluvial, 24
08150 — Parets del Vallès (Barcelona)
Ispanija
SRN: ES-MF-000000784

Produktas (-ai):

Katalogo numeris	Pavadinimas	Numatytoji paskirtis	Bazinis UDI-DI
213679	DG Fluid A	DG Fluid A ir DG Fluid B naudojami Grifols analizatorių skysčių sistemos praplovimui. Prieš naudojimą tirpalai turi būti praskiedžiami.	843658373FLUIDLZ
213678	DG Fluid B		

Klasifikacija: A klasės prietaisai pagal IVDR ES 2017/746 VIII priedo 5 taisyklę.

DIAGNOSTIC GRIFOLS, S.A. PAREIŠKIA, KAD PIRMIAU MINĖTAS PRODUKTAS ATITINKA 2017 M. BALANDŽIO 5 D. EUROPOS PARLAMENTO IR TARYBOS REGLAMENTĄ (ES) 2017/746 DĖL IN VITRO DIAGNOSTIKOS MEDICINOS PRIETAISŲ. VISI PATVIRTINAMIEJI DOKUMENTAI YRA SAUGOMI GAMINTOJO.

Pirmojo išleidimo data pagal IVDR: 2022 m. vasario 15 d.

Išleidimo vieta, data: Parets del Vallès, 2024 m. balandžio 9 d.

Parašas:

/parašas/ /spaudas/

Marta Genis Lumbreras
Techninės srities direktorius
Diagnostic Grifols, S.A.

Diagnostic Grifols, S.A.
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diagnostic@grifols.com

EU DECLARATION OF CONFORMITY

Manufacturer:

DIAGNOSTIC GRIFOLS, S.A.
Passeig Fluvial, 24
08150 – Parets del Vallès (Barcelona)
Spain
SRN: ES-MF-000000784

Affected Product(s):

Catalogue Number	Name	Intended Purpose	Basic UDI-DI
210346	DG Gel AB (x4)	Used in gel technique for confirming the antigens of the ABO system of human blood samples. The DG Gel AB (x4) card is intended for transfusional or investigational practices and for prenatal and perinatal immunohematology studies. For use in the manual method or with automated instruments.	843658373DGGEL001X7
210378	DG Gel ABO/Rh (CR)	Used in gel technique for determining the antigens of the ABO and Rh (D) systems and the reverse ABO group of human blood samples. The DG Gel ABO/Rh (CR) card is intended for transfusional or investigational practices and for prenatal and perinatal immunohematology studies. For use in the manual method or with automated instruments.	843658373DGGEL015XJ
210348	DG Gel ABO/Rh (2D) + Kell	Used in gel technique for determining the antigens of the ABO, Rh (D) and Kell systems and the reverse ABO group in human blood samples. The DG Gel ABO/Rh (2D) + Kell card is intended for transfusional or investigational practices and for prenatal and perinatal immunohematology studies. For use in the manual method or with automated instruments.	843658373DGGEL008XM
210352	DG Gel ABO/Rh + Kell (RT)	Used in gel technique for determining the antigens of the ABO, Rh (D) and Kell systems and the reverse ABO group in human blood samples. The DG Gel ABO/Rh + Kell (RT) card is intended for transfusional or investigational practices and for prenatal and perinatal immunohematology studies. For use in the manual method or with automated instruments.	843658373DGGEL013XE

GRIFOLS

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diagnostic@grifols.com

Catalogue Number	Name	Intended Purpose	Basic UDI-DI
210377	DG Gel T/S Poly	Used in gel technique for confirming the blood groups of the ABO and Rh (D) systems and for Indirect Antiglobulin Test. These tests permit the detection of ABO group and Rh antigens, the investigation of unexpected antibodies and the determination of blood compatibility in human blood samples. The DG Gel T/S Poly card is intended for transfusional or investigational practices and for prenatal and perinatal immunohematology studies. For use in the manual method or with automated instruments.	843658373DGGEL011XA

Classification: Class D devices according to Rule 2 of Annex VIII of the IVDR EU 2017/746.

Conformity Assessment Route: Annex IX from Regulation (EU) 2017/746.

Notified Body: BSI Group The Netherlands B.V., nº 2797.

Certificates issued by the Notified Body:

Product Name	IVDR certificates
DG Gel AB (x4)	IVDR 734695
DG Gel ABO/Rh (CR)	IVDR 734696
DG Gel ABO/Rh (2D) + Kell	IVDR 734705
DG Gel ABO/Rh + Kell (RT)	IVDR 734720
DG Gel T/S Poly	IVDR 734715

DIAGNOSTIC GRIFOLS, S.A. DECLARES, UNDER SOLE RESPONSIBILITY, THAT THE ABOVE-MENTIONED PRODUCTS ARE 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 Regulation (EU) 2022/1107.

GRIFOLS

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First emission date under IVDR: January 18th, 2023

Place, Date of Issue: Parets del Vallès, January 23rd, 2023

Signature:

Albert Hernández Botey
Technical Director
Diagnostic Grifols, S.A.

GRIFOLS

Diagnostic Grifols, S.A.
Passeig Fluvial, 24
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EU DECLARATION OF CONFORMITY

Manufacturer:

DIAGNOSTIC GRIFOLS, S.A.
Passeig Fluvial, 24
08150 – Parets del Vallès (Barcelona)
Spain
SRN: ES-MF-000000784

Affected Product(s):

Catalogue Number	Name	Intended Purpose	Basic UDI-DI
210600	Erytra Eflexis®	Erytra Eflexis® is a fully-automated analyzer designed to automate in vitro immunohematological testing of human blood utilizing gel card technology, including Blood Grouping, Antigen Typing, Antibody Screening, Antibody Identification, Compatibility Tests, and Direct Antiglobulin Tests. As a standalone analyzer or interfaced to the customer's Laboratory Information System (LIS), Erytra Eflexis® automates test processing functions and data management requirements using Grifols gel cards and digital image processing.	843658373EFLEXISWN

Classification: Class A devices according to Rule 5 of Annex VIII of the IVDR EU 2017/746.

DIAGNOSTIC GRIFOLS, S.A. DECLARES, UNDER SOLE RESPONSIBILITY, THAT THE ABOVE-MENTIONED PRODUCT ARE 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 emission date under IVDR: December 15th, 2021

Place, Date of Issue: Parets del Vallès, May 18th, 2022

Signature:

GRIFOLS
Diagnostic Grifols, S.A.

Albert Hernández Botey
Technical Director
Diagnostic Grifols, S.A.

Vertimas iš anglų kalbos

/GRIFOLS logotipas/

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ES ATITIKTIES DEKLARACIJA

Gamintojas: DIAGNOSTIC GRIFOLS, S.A.
Passeig Fluvial, 24
08150 – Parets del Valles (Barselona)
Ispanija
SRN: ES-MF-000000784

Produktas (-ai):

Katalogo numeris	Pavadinimas	Numatytoji paskirtis	Pagrindinis UDI-DI
210600	Erytra Eflexis®	Erytra Eflexis® yra pilnai automatizuotas analizatorius, skirtas in vitro imunohematologinių žmogaus kraujo tyrimų automatizavimui panaudojant gelio kortelių technologiją, įskaitant kraujo grupių nustatymą, antigenų tipų nustatymą, antikūnų atranką, antikūnų identifikavimą, suderinamumo tyrimus bei tiesioginius antiglobulino tyrimus. Kaip atskiras analizatorius arba sujungtas su kliento laboratorijos informacine sistema (LIS), Erytra Eflexis® automatizuoja tyrimų apdorojimo funkcijas ir duomenų valdymo reikalavimus, naudojant Grifols gelio korteles ir skaitmeninį vaizdų apdorojimą.	843658373EFLEXISWN

Klasifikacija: A klasės prietaisai pagal IVDR ES 2017/746 VIII priedo 5 taisyklę.

DIAGNOSTIC GRIFOLS, S.A., PRISIIMDAMA VISĄ ATSAKOMYBĘ, TVIRTINA, JOG AUKŠČIAU MINIMAS PRODUKTAS ATITINKA ATITINKA 2017 M. BALANDŽIO 5 D. EUROPOS PARLAMENTO IR TARYBOS REGLAMENTĄ (ES) 2017/746 DĖL IN VITRO DIAGNOSTIKOS MEDICINOS PRIETAISŲ. VISI PATVIRTINAMIEJI DOKUMENTAI IŠLIEKA GAMINTOJO ŽINIOJE.

Pirmojo leidimo data pagal IVDR: 2021 m. gruodžio 15 d.

Leidimo vieta ir data: Parets del Valles, 2022 m. gegužės 18 d.

Parašas: /parašas/ /spaudas/
Albert Hernandez Botey
Techninės dalies direktorius
Diagnostic Grifols, S.A.

Tikslus dokumento vertimas į lietuvių kalbą
Vertėja Akvilė Gegelevičienė
Data 2023-03-15
UAB Diamedica
Gėlių g. 2, Avižieniai, Lietuva

EU Quality Management System Certificate

Regulation (EU) 2017/746, Annex IX Chapter I and III

IVDR 734627 R000

Manufacturer: Diagnostic Grifols, S.A.

Address:
Passeig Fluvial, 24.
Parets del Vallès
Barcelona
08150
Spain

Single Registration Number: ES-MF-000000784

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/746, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class D devices, and self-test, near-patient test and companion diagnostic devices an Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2021-09-29**

Current Issue Date: **2023-01-18**

Starting Validity Date: **2023-01-18**

Expiry Date: **2026-09-28**

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EU Quality Management System Certificate

Regulation (EU) 2017/746, Annex IX Chapter I and III

IVDR 734627 R000

Device Schedule: Class D, C and B devices

Class D devices	Intended purpose
DG Gel AB (x4)	See IVDR 734695
DG Gel ABO/Rh (CR)	See IVDR 734696
DG Gel ABO/Rh (2D) + Kell	See IVDR 734705
DG Gel T/S Poly	See IVDR 734715
DG Gel ABO/Rh + Kell (RT)	See IVDR 734720
Serigrup Diana A1/B Serigrup Diana A2 Serigrup Diana 4	See IVDR 734729
Identisera Diana Identisera Diana Extend	See IVDR 734776
Identisera Diana P Identisera Extend P	See IVDR 734778
Serascan Diana 2 Serascan Diana 3 Serascan Diana 4	See IVDR 734779
Serascan Diana 2P Serascan Diana 3P Serascan Diana 4P	See IVDR 734780
Class C devices	**Intended purpose**
W0103 - Haematology / Haemostasis / Immunohaematology / Histology / Cytology IVP 3001 - In vitro diagnostic devices which require knowledge regarding agglutination tests.	Blood grouping gel cards and reagent red cells intended to be used to ensure blood compatibility and for other testing for blood transfusions and/or immunohematology studies using column agglutination technology.

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EU Quality Management System Certificate

Regulation (EU) 2017/746, Annex IX Chapter I and III

IVDR 734627 R000

Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2021-09-29	3275153	Issued
Current	3806107	Supplemented – Addition of DG Gel AB (x4), DG Gel ABO/Rh (CR), DG Gel ABO/Rh (2D) + Kell, DG Gel ABO/Rh + Kell (RT), DG Gel T/S Poly, Serigrup Diana, Identisera Diana and Serascan Diana devices

First Issue Date: **2021-09-29**

Current Issue Date: **2023-01-18**

Starting Validity Date: **2023-01-18**

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