

ATTESTATION CE / EC CERTIFICATE

Examen CE de type / EC Type Examination

ANNEXE V Directive 98/79/CE relative aux dispositifs médicaux de diagnostic in vitro

ANNEX V DIRECTIVE 98/79/EC concerning in vitro diagnostic medical devices

Fabricant / Manufacturer

DIAGAST

251 avenue Eugène Avinée, Eurasanté Parc

59120 LOOS FRANCE

Catégorie du(des) dispositif(s) / Device(s) category

Annexe II liste A : Détermination des groupes sanguins : système ABO, rhésus (C,c,D,E,e)

Annex II list A : Blood grouping determination : ABO system, rhesus (C,c,D,E,e)

Identification du(des) dispositif(s) / Identification of device(s)

Anti-A (ABO1), Anti-B (ABO2), Anti-A, B (ABO3), Anti-D (RH1) IgM I, Anti-D (RH1) IgM II, ANTI-D (RH1) TOTEM, ANTI-D (RH1) IgG, NEG CONTROL, ANTI-DCE (RH1,2,3), GROUPEKIT

Voir document complémentaire GMED / See GMED additional document

n° 39006

GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé P605187, un échantillon représentatif de la production est conforme aux exigences de l'annexe I de la directive 98/79/CE.

GMED certifies that, on the basis of the results contained in the file referenced P605187, a representative sample of the production complies with the requirements of the directive 98/79/EC, annex 1.

Début de validité / Effective date : May 16th, 2022 (included)

Valable jusqu'au / Expiry date : May 26th, 2025 (included)



On behalf of the President

Béatrice LYS

Technical Director

Ce document complémentaire GMED n° 39006 rev. 0 atteste de la validité du certificat CE n° 8383 rev. 7 au regard des informations listées ci-dessous.

This GMED additional document n° 39006 rev. 0 attests to the validity of CE certificate n° 8383 rev. 7 with regard to the information listed below.

Fabricant / Manufacturer :

DIAGAST
251 avenue Eugène Avinée,
Eurasanté Parc
59120 LOOS FRANCE

Identification des dispositifs / Identification of devices

- **Anti-A (ABO1)** - Clone 9113D10 Réf. **70501**, Réf. **70540**, Réf. **70114**
- **Anti-B (ABO2)** - Clone 9621A8 Réf. **70502**, Réf. **70541**, Réf. **70214**
- **Anti-A, B (ABO3)** - Clones 9113D10 + 152D12 Réf. **70503**, Réf. **70542**, Réf. **70314**
- **Anti-D (RH1) IgM I** - Clone P3X61 Réf. **71000**, Réf. **70543**, Réf. **71114**
- **Anti-D (RH1) IgM II** - Clone HM10 Réf. **71005**, Réf. **71214**
- **ANTI-D (RH1) IgG** - Clone HM16 Réf. **71020**, Réf. **71154**
- **ANTI-D (RH1) TOTEM** - Clones P3X61 + P3X21223B10 + P3X290 + P3X35 Réf. **71010**, Réf. **71104**, Réf. **70544**
- **ANTI-DCE (RH1,2,3)** - Clones P3X61 + P3X25513G8 + P3X234 Réf. **74111**, Réf. **72213**
- **NEG CONTROL** Réf. **79000** - Réf. **70545** - Réf. **79020**
- **GROUPAKIT** : Anti-A + Anti-B clone + Anti-A,B + Anti-D + NEG CONTROL Réf. **70888**

Codes GMDN / GMDN codes:

- 46442 – Anti-AB red blood cell grouping IVD, antibody
- 52532 – Anti-A red blood cell grouping IVD, antibody
- 52538 – Anti-B red blood cell grouping IVD, antibody
- 52550 – Anti-CDE blood cell grouping IVD, antibody
- 52647 – Anti-D red blood grouping IVD, antibody
- 45308 – ABO/ Rh(D) multiple blood grouping IVD, kit, agglutination
- 52705 – Antisera matrix (non-reactive) IVD, control

GMED	0459
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GMED - 39006 rev. 0



On behalf of the President
Béatrice LYS
Technical Director

/GMED logotipas/

SERTIFIKATO nr. 8383, red. 7
Išleista Paryžiuje 2012 m. gegužės 16 d.

EB SERTIFIKATAS

EB dizaino tyrimas (gaminio)
DIREKTYVOS 98/79/EB dėl in vitro diagnostikos medicinos prietaisų V PRIEDAS

Gamintojas

DIAGAST

**251 avenue Eugene Avinee, Eurasante Parc
59120 LOOS, PRANCŪZIJA**

Prietaiso (-ų) kategorija

II priedo A sąrašas: kraujo grupių nustatymas - ABO sistema, rezus (C, c, D, E, e)

Prietaiso (-ų) identifikacija

ANTI-A (ABO1), ANTI-B (ABO2), ANTI-A,B (ABO3), ANTI-D (RH1) IgM I, ANTI-D (RH1) IgM II, ANTI-D (RH1) TOTEM, ANTI-D (RH1) IgG, NEG CONTROL, ANTI-DCE (RH1, 2, 3), GROUPAKIT

Žr. GMED papildomą dokumentą nr. 39006.

GMED tvirtina, kad remiantis referentiniame faile P605187 pateiktais rezultatais, tipinis produkcijos pavyzdys atitinka reikalavimus, pateikiamus direktyvos 98/79/EB 1 priede.

Įsigaliojimo data: **2022 m. gegužės 16 d. (įskaitytinai)**

Galiojimo pabaigos data: **2025 m. gegužės 26 d. (įskaitytinai)**

/parašas/ /spaudas/

**Kompanijos prezidento vardu
Beatrice LYS
Techninis direktorius**

GMED – 8383 red. 7
Sertifikato atnaujinimas 8383-4

/rekvizitai/

/GMED logotipas/

GMED papildomas dokumentas nr. 39006, red. 0. Lapas 1/1
Failo nr. P605189
Išleista 2022 m. gegužės 16 d. Paryžiuje

Šis GMED papildomas dokumentas, nr. 39006, red. 0, patvirtina CE sertifikata nr. 8383, red. 7, atsižvelgiant į toliau nurodytą informaciją.

Gamintojas

DIAGAST
251 avenue Eugene Avinee, Eurasante Parc
59120 LOOS, PRANCŪZIJA

Priemonių identifikacija

- **ANTI-A** (ABO1) - klonas 9113D10, ref. 70501, ref. 70540, ref. 70114
- **ANTI-B** (ABO2) - klonas 9621A8, ref. 70502, ref. 70541, ref. 70214
- **ANTI-A,B** (ABO3) - klonai 9113D10 + 152D12, ref. 70503, ref. 70542, ref. 70314
- **ANTI-D (RH1) IgM I** - klonas P3X61, ref. 71000, ref. 70543, ref. 71114
- **ANTI-D (RH1) IgM II** - klonas HM10, ref. 71005, ref. 71214
- **ANTI-D (RH1) IgG** - klonas HM16, ref. 71020, ref. 71154
- **ANTI-D (RH1) TOTEM** - klonai P3X61 + P3X21223B10 + P3X290 + P3X35, ref. 71010, ref. 71104, ref. 70544
- **ANTI-DCE** (RH1, 2, 3) - klonai P3X61 + P3X25513G8 + P3X234, ref. 74111, ref. 72213
- **NEG CONTROL** ref. 79000 - ref. 70545 - ref. 79020
- **GROUPAKIT**: Anti-A + Anti-B klonas + Anti-A,B + Anti-D + NEG CONTROL, ref. 70888

GMDN kodai:

46442 – Anti-AB eritrocitų grupės nustatymas IVD, antikūnas
52532 – Anti-A eritrocitų grupės nustatymas IVD, antikūnas
52538 – Anti-B eritrocitų grupės nustatymas IVD, antikūnas
52550 – Anti-CDE eritrocitų grupės nustatymas IVD, antikūnas
52647 – Anti-D eritrocitų grupės nustatymas IVD, antikūnas
45308 – ABO/Rh(D) sudėtinis kraujo grupių nustatymas IVD, rinkinys, agliutinacija
52705 – Antiserumo matrica (nereaktyvi) IVD, kontrolė

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/parašas/ /spaudas/
Prezidento vardu
Beatrice LYS
Techninis direktorius

Tikslus dokumento vertimas į lietuvių kalbą
Vertėja Akvilė Gegelevičienė
Data 2023-09-04
UAB Diamedica
Gėlių g. 2, Avižieniai, Lietuva

/rekvizitai/



Diagast's Declaration

in relation to Regulation (EU) 2024/1860 amending Regulation (EU) 2017/746 (IVDR) as regards the transitional provisions for certain *in vitro* diagnostic medical devices, in particular with respect to the compliance of the devices and us, as their manufacturer, with the conditions for the continued placing on the market and putting into service

Manufacturer name	DIAGAST
Manufacturer address and contact details	251 Avenue Eugène Avinée – Parc Eurasanté – 59120 – Loos – France Tel : +33 (0)3 20 96 53 53 Fax : +33 (0)3 20 96 53 54
Single Registration Number (SRN)	Manufacturer: FR-MF-000012310 Importer: FR-IM-000036592

Notified body name	GMED
Notified body number	0459

We, as the manufacturer declare that the **devices** listed in the confirmation letter request (dated on: 02/10/2024) and we as their manufacturer are in compliance with the conditions listed in Article 110.3c of the IVDR for continued placing on the market and putting into service, namely by fulfilling the following conditions:

1) Devices which were self-declared under the IVDD and require notified body involvement under the IVDR

In case of devices for which the conformity assessment procedure pursuant to IVDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2022 and for which the conformity assessment procedure pursuant to IVDR requires the involvement of a notified body:

- Formal applications to the notified body in accordance with Section 4.3, first subparagraph of Annex VII IVDR for conformity assessment have been lodged by us to a notified body for the devices listed in the confirmation letter request (dated on: 02/10/2024).
- Signed written agreements is in place in accordance with Section 4.3, second subparagraph of Annex VII IVDR for the devices listed in the confirmation letter request (dated on: 02/10/2024).



DIAGAST

2) Directive Certificates

Directive Certificates covering the devices listed in the confirmation letter request (dated on: 02/10/2024) were issued after 25 May 2017, were valid on 26 May 2022 and have not been withdrawn afterwards.

Formal applications to the notified body in accordance with Section 4.3, first subparagraph of Annex VII IVDR for conformity assessment have been lodged by us for the devices listed in the attached letter and signed written agreements is in place in accordance with Section 4.3, second subparagraph of Annex VII IVDR.

3) Quality Management System (QMS)

QMS in accordance with Article 10(8) IVDR is in place and notified body has issued a certificate for the IVDR-compliant QMS (39430 issued by GMED).

4) Devices listed in the attached letter

- The devices continue to comply with the IVDD.
- There are no significant changes in the design and intended purpose.
- The devices do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

DIAGAST

Loos, 2nd October 2024

Stéphane REFREGIER, Quality & Regulatory Affairs Director



251, Avenue Eugène Avinée
Eurasanté Parc
59120 LOOS - FRANCE
Tel : +33 (0)3 20 96 53 53
Fax : +33 (0)3 20 96 53 54
Siret 343 445 375 00029
www.diagast.com



Paris, le 10 octobre 2024

Lettre de confirmation émise par l'Organisme Notifié
Notified Body Confirmation Letter
Référence : 40016 rev.0

[ENGLISH BELOW]

A qui de droit,

Confirmation du statut d'une demande formelle, d'un accord écrit et de la surveillance appropriée dans le cadre du règlement UE 2024/1860 modifiant le règlement (UE) 2017/746 en ce qui concerne les dispositions transitoires relatives à certains dispositifs médicaux de diagnostic in vitro.

Cette lettre confirme que, **GMED SAS**, Organisme Notifié désigné au titre du règlement (UE) 2017/746 (ci-après : RDIV) et identifié par le numéro **0459** sur NANDO, a reçu une demande formelle de certification conformément à l'annexe VII, section 4.3, premier alinéa, et a signé un accord écrit (contrat) conformément à l'annexe VII, section 4.3, deuxième alinéa dudit Règlement avec le fabricant suivant :

DIAGAST
251 avenue Eugène Avinée
Eurasanté Parc
59120 LOOS
SRN : FR-MF-000012310

Les dispositifs couverts par la demande formelle et l'accord écrit mentionnés ci-dessus sont identifiés dans les tableaux suivants. Le tableau 1 identifie les dispositifs pour lesquels une demande formelle a été reçue, un accord écrit conclu et pour lesquels GMED SAS est également responsable de la surveillance appropriée des dispositifs correspondants au titre de la Directive 98/79/CE (DDIV).

Dans le cas de dispositifs couverts par des certificats délivrés au titre de la directive 98/79/CE qui ont expiré après le 26 mai 2022 et avant le 09 Juillet 2024, sans avoir été retirés, cette lettre confirme également que le fabricant a signé l'accord écrit avant la date d'expiration desdits certificats ou a fourni la preuve qu'une Autorité Compétente d'un État Membre a accordé une dérogation conformément à l'article 54 du règlement (UE) 2017/746 ou a demandé conformément à l'article 92 du règlement (UE) 2017/746, de mettre en œuvre la procédure d'évaluation de la conformité applicable, avant le 09 Juillet 2024 pour les dispositifs concernés.



Je soussigné... *Me Benveniste*
Notaire à Lille, 99 rue Nationale
Certifie la (les) signature(s) apposée(s) ci-dessus

Les délais de transition qui s'appliquent aux dispositifs couverts par la présente lettre, sous réserve que le fabricant continue de respecter les autres conditions spécifiées à l'article 110.3quater du Règlement (UE) 2017/746 (amendé par le Règlement (UE) 2024/1860), sont indiqués ci-dessous :

- 31 décembre 2027 pour les dispositifs couverts par un certificat IVDD, quelle que soit leur classe de risque selon le RDIV ;
- Pour les dispositifs ne nécessitant pas l'intervention d'un organisme notifié au titre de la DDIV, mais pour lesquels leur intervention est désormais nécessaire au titre du RDIV et pour lesquels une déclaration de conformité a été établie avant le 26 mai 2022 conformément à la directive 98/79/CE, les dates suivantes s'appliquent :
 - 31 décembre 2027, pour les dispositifs de classe D ;
 - 31 décembre 2028, pour les dispositifs de classe C ;
 - 31 décembre 2029, pour les dispositifs de classe B et pour les dispositifs de classe A mis sur le marché à l'état stérile

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2024/1860 amending Regulation (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

*This letter confirms that, **GMED SAS**, a Notified Body designated against Regulation (EU) 2017/746 (hereafter: IVDR) and identified by the number **0459** on NANDO, has received a formal application for certification in accordance with section 4.3, first subparagraph of Annex VII, and has signed a written agreement (contract) in accordance with section 4.3, second subparagraph of Annex VII of IVDR with the following manufacturer:*

DIAGAST
251 avenue Eugène Avinée
Eurasanté Parc
59120 LOOS
SRN: FR-MF-000012310

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an IVDR application has been received, written agreement concluded and for which GMED SAS is also responsible for appropriate surveillance of the corresponding devices under Directive 98/79/EC.

In the case of devices covered by certificates issued under Directive 98/79/CE (IVDD) that expired after 26 May 2022 and before 09 July 2024, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under IVDR by the date of IVDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 54 or Article 92 of the IVDR respectively, by the 09 July 2024 for the relevant devices.



The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 110.3c of IVDR (as amended by (EU) 2024/1860), are shown below:

- 31 December 2027 for devices covered by an IVDD certificate regardless of their risk class under the IVDR
- For devices not requiring the involvement of a notified body under the IVDD, but requiring it under the IVDR and for which a declaration of conformity was drawn up prior to 26 May 2022 in accordance with Directive 98/79/EC, the following dates apply:
 - 31 December 2027, for class D devices,
 - 31 December 2028, for class C devices,
 - 31 December 2029, for class B devices and for class A devices placed on the market in sterile condition.

Pour le compte de GMED SAS,
On behalf of GMED SAS,

DocuSigned by:
Béatrice Lys
EF33BDA9BA04A3...

Béatrice LYS
Directeur Technique
Technical Director

Tableau 1 : Dispositifs couverts par la présente lettre et pour lesquels GMED SAS est également responsable de la surveillance appropriée des dispositifs correspondants dans le cadre de la Directive applicable

Table 1: Devices covered by this letter and for which GMED SAS is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive

Device name and/or Basic UDI-DI (under IVDR application)	IVDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the IVDR device is a substitute device, identification of the corresponding IVDD device	IVDD/ Certificate Reference(s) of the devices under IVDR application, and the NB Identification
59659 Hemalys 1 A1, B Basic UDI-DI 3661562DEMTBGRBCXXXXXXXXT2	D	N/A	8428 rev. 11 10492 rev. 21
59661 Hemalys 1 A1, A2, B, O Basic UDI-DI 3661562DEMTBGRBCXXXXXXXXT2	D	N/A	8428 rev. 11 10492 rev. 21
59663 Hemalys 1 A1, B Basic UDI-DI 3661562DEMTBGRBCXXXXXXXXT2	D	N/A	8428 rev. 11 10492 rev. 21
79960 DuoLys (ABO-RH-KEL1) Basic UDI-DI 3661562DEMTBGRXXXXXXXXXXPE	D	N/A	8394 rev. 9 10492 rev. 21
79962 PhenoLys Basic UDI-DI 3661562DEMTBGRXXXXXXXXXXPE	D	N/A	8394 rev. 9 10492 rev. 21
79964 Groupa 2 Lys Basic UDI-DI 3661562DEMTBGRXXXXXXXXXXPE	D	N/A	8394 rev. 9 10492 rev. 21
79965 Groupa A1 Lys Basic UDI-DI 3661562DEMTBGR2XXXXXXXXXUQ	D	N/A	8394 rev. 9 10492 rev. 21
79966 Pheno 1,2 Lys Basic UDI-DI 3661562DEMTBGR1XXXXXXXXXTZ	D	N/A	8394 rev. 9 10492 rev. 21
79969 Groupa DVI Lys Basic UDI-DI 3661562DEMTBGRXXXXXXXXXXPE	D	N/A	8394 rev. 9 10492 rev. 21
79970 DuoLys v2 Basic UDI-DI 3661562DEMTBGR1XXXXXXXXXTZ	D	N/A	8394 rev. 9 10492 rev. 21
79971 PhenoLys v2 Basic UDI-DI 3661562DEMTBGR1XXXXXXXXXTZ	D	N/A	8394 rev. 9 10492 rev. 21
79972 Pheno 1,2 Lys v2 Basic UDI-DI 3661562DEMTBGR1XXXXXXXXXTZ	D	N/A	8394 rev. 9 10492 rev. 21
79990 ABDVI-Lys v2 Basic UDI-DI 3661562DEMTBGRXXXXXXXXXXPE	D	N/A	36142 rev. 1 10492 rev. 21
79991 ABD-Lys v2 Basic UDI-DI 3661562DEMTBGR1XXXXXXXXXTZ	D	N/A	36142 rev. 1 10492 rev. 21

Device name and/or Basic UDI-DI (under IVDR application)	IVDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	Device name and/or Basic UDI-DI (under IVDR application)	Device name and/or Basic UDI-DI (under IVDR application)
70501 ANTI-A (ABO1) Basic UDI-DI 3661562DMANUBGRXXXXXXXXXE7	D	N/A	8383 rev. 7 10492 rev. 21
70502 ANTI-B (ABO2) Basic UDI-DI 3661562DMANUBGRXXXXXXXXXE7	D	N/A	8383 rev. 7 10492 rev. 21
70503 ANTI-A,B (ABO3) Basic UDI-DI 3661562DMANUBGRXXXXXXXXXE7	D	N/A	8383 rev. 7 10492 rev. 21
70540 ANTI-A (ABO1) Basic UDI-DI 3661562DMANUBGRXXXXXXXXXE7	D	N/A	8383 rev. 7 10492 rev. 21
70541 ANTI-B (ABO2) Basic UDI-DI 3661562DMANUBGRXXXXXXXXXE7	D	N/A	8383 rev. 7 10492 rev. 21
70542 ANTI-A,B (ABO3) Basic UDI-DI 3661562DMANUBGRXXXXXXXXXE7	D	N/A	8383 rev. 7 10492 rev. 21
70543 ANTI-D (RH1) IgM I Basic UDI-DI 3661562DMANUBGRDXXXXXXXX2B	D	N/A	8383 rev. 7 10492 rev. 21
70544 ANTI-D (RH1) TOTEM Basic UDI-DI 3661562DMANUBGRDXXXXXXXX2B	D	N/A	8383 rev. 7 10492 rev. 21
70888 GROUPEKIT Basic UDI-DI 3661562DMANUBGRXXXXXXXXXE7	D	N/A	8383 rev. 7 10492 rev. 21
71000 ANTI-D (RH1) IgM I Basic UDI-DI 3661562DMANUBGRDXXXXXXXX2B	D	N/A	8383 rev. 7 10492 rev. 21
71005 ANTI-D (RH1) IgM II Basic UDI-DI 3661562DMANUBGRDXXXXXXXX2B	D	N/A	8383 rev. 7 10492 rev. 21
71010 ANTI-D (RH1) TOTEM Basic UDI-DI 3661562DMANUBGRDXXXXXXXX2B	D	N/A	8383 rev. 7 10492 rev. 21
71020 ANTI-D (RH1) IgG Basic UDI-DI 3661562DMANUBGRDXXXXXXXX2B	D	N/A	8383 rev. 7 10492 rev. 21
74111 ANTI-DCE (RH1,2,3) Basic UDI-DI 3661562DMANUBGRDXXXXXXXX2B	D	N/A	8383 rev. 7 10492 rev. 21
79000 NEG CONTROL Basic UDI-DI 3661562DMANUBGRXXXXXXXXXE7	D	N/A	8383 rev. 7 10492 rev. 21



Device name and/or Basic UDI-DI (under IVDR application)	IVDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the IVDR device is a substitute device, identification of the corresponding IVDD device	IVDD/ Certificate Reference(s) of the devices under IVDR application, and the NB Identification
73028 AGH ANTI-IgG PK Basic UDI-DI 3661562DPKAHGXXXXXXXXXXQW	D	N/A	9577 rev. 16
73020 ANTI-Fya (FY1) PK Basic UDI-DI 3661562DPKBGREXTXXXXXXXXG4	D	N/A	9577 rev. 16
73021 ANTI-Fyb (FY2) PK Basic UDI-DI 3661562DPKBGREXTXXXXXXXXG4	D	N/A	9577 rev. 16
73022 ANTI-Jka (JK1) PK Basic UDI-DI 3661562DPKBGREXTXXXXXXXXG4	D	N/A	9577 rev. 16
73023 ANTI-Jkb (JK2) PK Basic UDI-DI 3661562DPKBGREXTXXXXXXXXG4	D	N/A	9577 rev. 16
73026 NEG CONTROL PK Basic UDI-DI 3661562DPKBGREXTXXXXXXXXG4	D	N/A	9577 rev. 16
79967 ABD-Lys Basic UDI-DI 3661562DEMTBGRXXXXXXXXXXPE	D	N/A	8248 rev. 5 10492 rev. 21
B10347 HEMA CELLS A1, B (PK1) Basic UDI-DI 3661562DPKBGRBCXXXXXXXXXXYK	D	N/A	8615 rev. 8 10492 rev. 21
B10348 HEMA CELLS A2 (PK1) Basic UDI-DI 3661562DPKBGRBCXXXXXXXXXXYK	D	N/A	8615 rev. 8 10492 rev. 21
B10349 HEMA CELLS O (PK1) Basic UDI-DI 3661562DPKBGRBCXXXXXXXXXXYK	D	N/A	8615 rev. 8 10492 rev. 21
B10903 HEMA CELLS A1, B (PK2) Basic UDI-DI 3661562DPKBGRBCXXXXXXXXXXYK	D	N/A	8615 rev. 8 10492 rev. 21
B10904 HEMA CELLS A2 (PK2) Basic UDI-DI 3661562DPKBGRBCXXXXXXXXXXYK	D	N/A	8615 rev. 8 10492 rev. 21
B10905 HEMA CELLS O (PK2) Basic UDI-DI 3661562DPKBGRBCXXXXXXXXXXYK	D	N/A	8615 rev. 8 10492 rev. 21
51999 HEMATEST A1, A2, B, O Basic UDI-DI 3661562DMANUBGRBCXXXXXXXXMV	D	N/A	38634 rev. 2
58950 HEMATEST A1, B Basic UDI-DI 3661562DMANUBGRBCXXXXXXXXMV	D	N/A	38634 rev. 2



Device name and/or Basic UDI-DI (under IVDR application)	IVDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the IVDR device is a substitute device, identification of the corresponding IVDD device	IVDD/ Certificate Reference(s) of the devices under IVDR application, and the NB Identification
74011 ANTI-c (RH4) Basic UDI-DI 3661562DMANUBGRPHEXXXXR5	D	N/A	9522 rev. 7 10492 rev. 21
74221 ANTI-C (RH2) Basic UDI-DI 3661562DMANUBGRPHEXXXXR5	D	N/A	9522 rev. 7 10492 rev. 21
74311 ANTI-E (RH3) Basic UDI-DI 3661562DMANUBGRPHEXXXXR5	D	N/A	9522 rev. 7 10492 rev. 21
74611 ANTI-e (RH5) Basic UDI-DI 3661562DMANUBGRPHEXXXXR5	D	N/A	9522 rev. 7 10492 rev. 21
74711 ANTI-K (KEL1) Basic UDI-DI 3661562DMANUBGRPHEXXXXR5	D	N/A	9522 rev. 7 10492 rev. 21
74911 PHENOKIT Basic UDI-DI 3661562DMANUBGRPHEXXXXR5	D	N/A	9522 rev. 7 10492 rev. 21
78003 ANTI-Jka (JK1) Basic UDI-DI 3661562DMANUBGREXTXXXXXZ7	D	N/A	9577 rev. 16
78004 ANTI-Jkb (JK2) Basic UDI-DI 3661562DMANUBGREXTXXXXXZ7	D	N/A	9577 rev. 16
78014 ANTI-Fya (FY1) Basic UDI-DI 3661562DMANUBGREXTXXXXXZ7	D	N/A	9577 rev. 16
78015 ANTI-Fyb (FY2) Basic UDI-DI 3661562DMANUBGREXTXXXXXZ7	D	N/A	9577 rev. 16
76118 AGH MAESTRIA C3D Basic UDI-DI 3661562DMANUAHGXXXXXXXXX68	D	N/A	9280 rev. 8 10492 rev. 21
76218 AGH MAESTRIA IGG Basic UDI-DI 3661562DMANUAHGXXXXXXXXX68	D	N/A	9280 rev. 8 10492 rev. 21
76318 AGH MAESTRIA IGG+C3D Basic UDI-DI 3661562DMANUAHGXXXXXXXXX68	D	N/A	9280 rev. 8 10492 rev. 21
59852 HEMASCREEN Basic UDI-DI 3661562DEMTABSRBC2XXXXX6N	D	N/A	9577 rev. 16
59855 HEMA-IDENT Basic UDI-DI 3661562DEMTABSRBC2XXXXX6N	D	N/A	9577 rev. 16
79900 MagneLys Basic UDI-DI 3661562BEMTMAGSOLXXXXXZM	B	N/A	N/A – Dispositif ne nécessitant pas l'intervention d'un Organisme Notifié
20505 QR ANTI-S (MNS3) Basic UDI-DI 3661562CEMTBGREXTXXXXX5Y	C	N/A	N/A – Dispositif ne nécessitant pas l'intervention d'un Organisme Notifié

Device name and/or Basic UDI-DI (under IVDR application)	IVDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the IVDR device is a substitute device, identification of the corresponding IVDD device	IVDD/ Certificate Reference(s) of the devices under IVDR application, and the NB Identification
20506 QR ANTI-s (MNS4) Basic UDI-DI 3661562CEMTBGREXTXXXXX5Y	C	N/A	N/A – Dispositif ne nécessitant pas l'intervention d'un Organisme Notifié
20508 QR ANTI-k (KEL2) Basic UDI-DI 3661562CEMTBGREXTXXXXX5Y	C	N/A	N/A – Dispositif ne nécessitant pas l'intervention d'un Organisme Notifié
78005 ANTI-M (MNS1) Basic UDI-DI 3661562CMANUBGREXTXXXXXJ	C	N/A	N/A – Dispositif ne nécessitant pas l'intervention d'un Organisme Notifié
78006 ANTI-N (MNS2) Basic UDI-DI 3661562CMANUBGREXTXXXXXJ	C	N/A	N/A – Dispositif ne nécessitant pas l'intervention d'un Organisme Notifié
78007 ANTI-S (MNS3) Basic UDI-DI 3661562CMANUBGREXTXXXXXJ	C	N/A	N/A – Dispositif ne nécessitant pas l'intervention d'un Organisme Notifié
78008 ANTI-s (MNS4) Basic UDI-DI 3661562CMANUBGREXTXXXXXJ	C	N/A	N/A – Dispositif ne nécessitant pas l'intervention d'un Organisme Notifié
78009 ANTI-Lea (LE1) Basic UDI-DI 3661562CMANUBGREXTXXXXXJ	C	N/A	N/A – Dispositif ne nécessitant pas l'intervention d'un Organisme Notifié
78010 ANTI-Leb (LE2) Basic UDI-DI 3661562CMANUBGREXTXXXXXJ	C	N/A	N/A – Dispositif ne nécessitant pas l'intervention d'un Organisme Notifié
78011 ANTI-P1 Basic UDI-DI 3661562CMANUBGREXTXXXXXJ	C	N/A	N/A – Dispositif ne nécessitant pas l'intervention d'un Organisme Notifié
78013 ANTI-Cw (RH8) Basic UDI-DI 3661562CMANUBGREXTXXXXXJ	C	N/A	N/A – Dispositif ne nécessitant pas l'intervention d'un Organisme Notifié

Device name and/or Basic UDI-DI (under IVDR application)	IVDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the IVDR device is a substitute device, identification of the corresponding IVDD device	IVDD/ Certificate Reference(s) of the devices under IVDR application, and the NB Identification
78016 ANTI-k (KEL2) Basic UDI-DI 3661562CMANUBGREXTXXXXXXJ	C	N/A	N/A – Dispositif ne nécessitant pas l'intervention d'un Organisme Notifié
73024 ANTI-S (MNS3) PK Basic UDI-DI 3661562CPKBGREXTXXXXXXEF	C	N/A	N/A – Dispositif ne nécessitant pas l'intervention d'un Organisme Notifié
73025 ANTI-s (MNS4) PK Basic UDI-DI 3661562CPKBGREXTXXXXXXEF	C	N/A	N/A – Dispositif ne nécessitant pas l'intervention d'un Organisme Notifié
73032 ANTI-s (MNS4) PK Basic UDI-DI 3661562CPKBGREXTXXXXXXEF	C	N/A	N/A – Dispositif ne nécessitant pas l'intervention d'un Organisme Notifié
73070 ANTI-M (MNS1) PK Basic UDI-DI 3661562CPKBGREXTXXXXXXEF	C	N/A	N/A – Dispositif ne nécessitant pas l'intervention d'un Organisme Notifié
73071 ANTI-N (MNS2) PK Basic UDI-DI 3661562CPKBGREXTXXXXXXEF	C	N/A	N/A – Dispositif ne nécessitant pas l'intervention d'un Organisme Notifié
20401 Q _R Anti-D WEAK Basic UDI-DI 3661562DEMTBGRPHEWXXXXXVK	D	N/A	21598 rev. 5 10492 rev. 21
20501 Q _R ANTI-Fya (FY1) Basic UDI-DI 3661562DEMTBGREXTXXXXXX7M	D	N/A	9577 rev. 16
20503 Q _R ANTI-Jka (JK1) Basic UDI-DI 3661562DEMTBGREXTXXXXXX7M	D	N/A	9577 rev. 16
20504 Q _R ANTI-Jkb (JK2) Basic UDI-DI 3661562DEMTBGREXTXXXXXX7M	D	N/A	9577 rev. 16
20507 Q _R NEG CONTROL Basic UDI-DI 3661562DEMTBGREXTXXXXXX7M	D	N/A	38968 rev. 0 10492 rev. 21
20509 Q _R ANTI-Fyb (FY2) Basic UDI-DI 3661562DEMTBGREXTXXXXXX7M	D	N/A	9577 rev. 16
59550 HEMASCREEN POOL Basic UDI-DI 3661562DEMTABSRBC1XXXXX	D	N/A	9577 rev. 16
59502 SERA CQI Basic UDI-DI 3661562DIQCABS1XXXXXXXXXCD	D	N/A	10499 rev. 4 10492 rev. 21
59507 ABS CQI Basic UDI-DI 3661562DIQCABS2XXXXXXXXX6Y	D	N/A	9577 rev. 16

Device name and/or Basic UDI-DI (under IVDR application)	IVDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the IVDR device is a substitute device, identification of the corresponding IVDD device	IVDD/ Certificate Reference(s) of the devices under IVDR application, and the NB Identification
59503 SERA CQI FYA Basic UDI-DI 3661562DIQCABS1XXXXXXXXXCD	D	N/A	10499 rev. 4 10492 rev. 21
79070 ABTest Card Basic UDI-DI 3661562DCARDBGR2XXXXXXXXXST	D	N/A	32801 rev. 4 10492 rev. 21
79080 ABTest MULTI Basic UDI-DI 3661562DCARDBGR2XXXXXXXXXST	D	N/A	32800 rev. 3 10492 rev. 21
79090 ABTest Card EN-DE Basic UDI-DI 3661562DCARDBGR2XXXXXXXXXST	D	N/A	32801 rev. 4 10492 rev. 21
79100 ABTest Card ES-PT Basic UDI-DI 3661562DCARDBGR2XXXXXXXXXST	D	N/A	32801 rev. 4 10492 rev. 21
79843 ScreenLys 2 Basic UDI-DI 3661562DEMTABSXXXXXXXXXXJB	D	N/A	9577 rev. 16
79853 ScreenLys Basic UDI-DI 3661562DEMTABSXXXXXXXXXXJB	D	N/A	9577 rev. 16
79854 CrossLys Basic UDI-DI 3661562DEMTABSXXXXXXXXXXJB	D	N/A	9577 rev. 16
79861 ScreenLys Plate Basic UDI-DI 3661562DEMTABSXXXXXXXXXXJB	D	N/A	9577 rev. 16
59857 I-Mag Screen Basic UDI-DI 3661562DEMTABSRBCXXXXXXXXMP	D	N/A	9577 rev. 16
59859 I-Mag Ident Basic UDI-DI 3661562DEMTABSRBC3XXXXXXXX73	D	N/A	9577 rev. 16
40102 ABD PAD Basic UDI-DI 3661562DPADBGRXXXXXXXXXX2X	D	N/A	33642 rev. 2 10492 rev. 21
79069 SAFETY TEST ABO Basic UDI-DI 3661562DCARDBGR1XXXXXXXXXZ4	D	N/A	24618 rev. 3 10492 rev. 21
79074 SAFETY CARD AB Basic UDI-DI 3661562DCARDBGR1XXXXXXXXXZ4	D	N/A	24618 rev. 3 10492 rev. 21
79075 SAFETY CARD AB Basic UDI-DI 3661562DCARDBGR1XXXXXXXXXZ4	D	N/A	24618 rev. 3 10492 rev. 21
79076 SAFETY CARD AB Basic UDI-DI 3661562DCARDBGR1XXXXXXXXXZ4	D	N/A	24618 rev. 3 10492 rev. 21
79300 DC-Lys Basic UDI-DI 3661562BEMTDATXXXXXXXXXXJE	B	N/A	N/A – Dispositif ne nécessitant pas l'intervention d'un Organisme Notifié

Device name and/or Basic UDI-DI (under IVDR application)	IVDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the IVDR device is a substitute device, identification of the corresponding IVDD device	IVDD/ Certificate Reference(s) of the devices under IVDR application, and the NB Identification
69305 NanoLys Gel Basic UDI-DI 3661562BEMTGELXXXXXXXXXJH	B	N/A	N/A – Dispositif ne nécessitant pas l'intervention d'un Organisme Notifié
69312 I-Mag Diluent Basic UDI-DI 3661562BEMTABSDILXXXXXXXXH9	B	N/A	N/A – Dispositif ne nécessitant pas l'intervention d'un Organisme Notifié
20000 Q _R IRONMAG Basic UDI-DI 3661562BEMTMAGBEADXXXXXXXXZE	B	N/A	N/A – Dispositif ne nécessitant pas l'intervention d'un Organisme Notifié
79880 Blue Control Basic UDI-DI 3661562BEMTDISPENSQCXXXRS	B	N/A	N/A – Dispositif ne nécessitant pas l'intervention d'un Organisme Notifié
90871 QWALYS INTERPRETATION SOFTWARE Basic UDI-DI 3661562DEMTSWXXXXXXXXXXY4	D	N/A	N/A – Dispositif ne nécessitant pas l'intervention d'un Organisme Notifié

Historique de révision de la lettre
Confirmation Letter Revision History

Date	Révision/Revision	Action
10/10/2024	40016 rev. 0	Première émission Initial issuance

Pour toute question concernant le statut ou la validité de cette lettre, veuillez contacter :

g-med-certificats@lne-gmed.com

For any query about the status of validity of this letter, please contact:

g-med-certificats@lne-gmed.com

APOSTILLE
(Convention de la Haye du 03 Octobre 1961)

1. **République Française**
Le présent acte public
2. a été signé par David BENVENISTE
3. agissant en qualité de notaire associé
4. est revêtu du sceau/timbre de son Etude sise à LILLE
5. à DOUAI
6. le 04 Avril 2025
7. par le Procureur Général
8. sous le n° 2025/1907
9. Sceau :
10. Signature :

P/Le Procureur Général

Barthélemy COUDEVILLE
Substitut général

"L'Apostille confirme seulement l'authenticité de la signature, du sceau ou timbre sur le document. Elle ne signifie pas que le document est correct ou que la République Française approuve son contenu".

Nombre de page(s) : 12.



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:


GRIFOLS
Diagnostic Grifols, S.A.

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

ES ATTIKTIES 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.



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 Dürdingen
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](http://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

Marta Carnielli
Head of Notified Body IVD

Issue date: 2023-10-04



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



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

**Igaliotas
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 ženkliniu, 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

Išleidimo data: 2023-10-04

/parašas/
Marta Carnielli
Notifikuotosios įstaigos vadovas, IVD



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

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
210344	DG Gel Anti-IgG	Used in gel technique for Direct and Indirect Antiglobulin Tests. These tests permit the detection of sensitized red blood cells, screening and identification of unexpected antibodies, the determination of blood compatibility, red blood cell typing and antibody titration in human blood samples. The DG Gel Anti-IgG 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.	843658373DGGEL017XN
210342	DG Gel Coombs	Used in gel technique for Direct and Indirect Antiglobulin Tests. These tests permit the detection of sensitized red blood cells, screening and identification of unexpected antibodies, the determination of blood compatibility, red blood cell typing and antibody titration in human blood samples. The DG Gel Coombs 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.	843658373DGGEL018XQ
210345	DG Gel DC Scan	Used in gel techniques for the evaluation of the Direct Antiglobulin Test. This test permits the differentiation of red blood cells sensitized in vivo by IgG type immunoglobulins or the complement C3d fractions in human blood samples. The DG Gel DC Scan card is intended for the investigation of hemolytic disease of the newborn, transfusion reactions, and autoimmune hemolytic anemia. For use in the manual method or with automated instruments.	843658373DGGEL019XS
210375	DG Gel Neutral/Coombs	Used in gel technique for the saline and enzymatic test (Neutral), and for the Direct and Indirect Antiglobulin Tests (Coombs). These tests permit the detection of sensitized red blood cells, screening and identification of unexpected antibodies, the determination of blood compatibility, red blood cell typing and antibody titration in human blood samples. The DG Gel Neutral/Coombs 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.	843658373DGGEL020XB
210343	DG Gel Neutral	Used in gel technique for saline and enzymatic tests and as a control microtube. These tests permit the detection of ABO group antibodies, screening and identification of unexpected antibodies, the determination of blood compatibility, red blood cell typing and antibody titration in human blood samples. The DG Gel Neutral 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.	843658373DGGEL021XD

Catalogue Number	Name	Intended Purpose	Basic UDI-DI
210127	DG Gel DC Scan Plus	DG Gel DC Scan Plus card is used in gel technique for the evaluation of the Direct Antiglobulin Test. This test permits the differentiation of red blood cells sensitized in vivo by IgG, IgA and IgM type immunoglobulins and/or with the complement C3b, C3d and C4b fractions in human blood samples. The DG Gel DC Scan Plus card is intended for the investigation of those clinical situations where the presence of hemolysis has been established, or is suspected, to distinguish immune from nonimmune hemolytic anaemia. For use in the manual method or with automated instruments.	843658373DGGEL024XK

Classification: Class C 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., n° 2797.

Certificates issued by the Notified Body: IVDR 734627.

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: September 29th, 2021

Place, Date of Issue: Pareds del Vallès, January 10th, 2023

Signature:


GRIFOLS
 Diagnostic Grifols, S.A.

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

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
210700	DG Reader Net	<p>The DG Reader Net is a device designed to read, interpret, and report the results of the processed Grifols gel cards. The instrument also identifies Grifols gel cards by reading their barcodes.</p> <p>As a stand-alone or interfaced to the customer's Laboratory Information System (LIS), the instrument automates data management requirements using Grifols gel cards and digital image processing.</p>	843658373DGREADERNET77

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 17th, 2021

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.

ES ATITIKTIES DEKLARACIJA

Gamintojas:

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

Susijęs (-ę) produktas (-ai):

Katalogo numeris	Pavadinimas	Numatyta paskirtis	Bazinis UDI-DI
210700	DG Reader Net	DG Reader Net yra prietaisas, skirtas apdorotoms Grifols gelio kortelėms nuskaityti, interpretuoti ir pateikti rezultatus. Prietaisas taip pat identifikuoja Grifols gelio korteles nuskaitydamas jų brūkšninius kodus. Kaip atskiras arba sujungtas su kliento laboratorijos informacine sistema (LIS), prietaisas automatizuoja duomenų valdymo reikalavimus naudojant Grifols gelio korteles ir skaitmeninį vaizdų apdorojimą.	843658373DGREADERNET77

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

DIAGNOSTIC GRIFOLS, S.A. SAVO ATSAKOMYBE PAREIŠKIA, KAD PIRMIAU MINĖTAS GAMINYS 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 17 d.

Leidimo vieta ir data:

2024 m. balandžio 9 d.

Parašas:

/parašas/ /spaudas/

Marta Genis Lumbreras
Techninio skyriaus vadovas
Diagnostic Grifols, S.A.

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
210363	DG Spin	The DG Spin centrifuge is a device specifically designed to centrifuge Grifols gel cards.	843658373DGSPINPD

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: May 21st, 2021

Place, Date of Issue: Parets del Vallès, January 10th, 2023

Signature:


GRIFOLS
Diagnostic Grifols, S.A.

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

/GRIFOLS logotipas/

DIAGNOSTIC GRIFOLS, S.A.
Passeig Fluvial, 24
08150 – Parets del Valles
Barcelona – Ispanija
Tel. (34) 935 710 400
Faks. (34) 935 710 373
diagnostic@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	Pagrindinis UDI-DI
210363	DG Spin	DG Spin centrifuga - tai prietaisas, specialiai sukurtas Grifols gelio kortelėms centrifuguoti.	843658373DGSPINPD

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. gegužės 21 d.

Leidimo vieta ir data: Parets del Valles, 2023 m. sausio 10 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 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
213734	DG Therm	The DG Therm Incubator is a device specifically designed to incubate Grifols gel cards and/or sample tubes at 37 °C for immunohematology applications.	843658373DG THERMXF

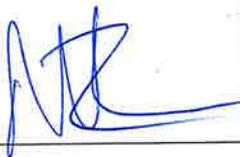
Classification: Class A devices according to Rule 5 of Annex VIII of the IVDR EU 2017/746.

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: April 22th, 2021

Place, Date of Issue: Parets del Vallès, January 10th, 2023

Signature:


GRIFOLS
Diagnostic Grifols, S.A.

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

/GRIFOLS logotipas/

DIAGNOSTIC GRIFOLS, S.A.
Passeig Fluvial, 24
08150 – Parets del Valles
Barcelona – Ispanija
Tel. (34) 935 710 400
Faks. (34) 935 710 373
diagnostic@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	Pagrindinis UDI-DI
213734	DG Therm	DG Therm inkubatorius - tai prietaisas, specialiai sukurtas Grifols gelio kortelėms ir (ar) mėgintuvėliams su mėginiais inkubuoti 37°C temperatūroje, atliekant imunohematologinius tyrimus.	843658373DGTHERMXF

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. balandžio 22 d.

Leidimo vieta ir data: Parets del Valles, 2023 m. sausio 10 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:

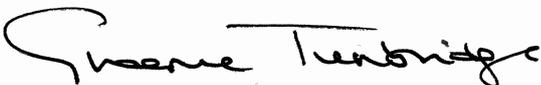
Passeig Fluvial, 24.
Parets del Vallès
Barcelona
08150
Spain

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: **2023-05-09**

Starting Validity Date: **2023-05-09**

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-CDE	See IVDR 734697
DG Gel ABO/Rh	See IVDR 734698
DG Gel ABO/Rh (2D)	See IVDR 734699
DG Gel Anti-D	See IVDR 734700
DG Gel Confirm	See IVDR 734701
DG Gel CT	See IVDR 734702
DG Gel ABO/Rh (2D) + Kell	See IVDR 734705
DG Gel Rh Pheno	See IVDR 734713
DG Gel Rh Pheno + Kell	See IVDR 734714
DG Gel T/S Poly	See IVDR 734715
DG Gel Confirm P	See IVDR 734716
DG Gel ABO/Rh + Kell (RT)	See IVDR 734720
DG Gel Newborn	See IVDR 734721
DG Gel ABO/Rh (2D) (RT)	See IVDR 734722
DG Gel ABO/Rh (2DVI-)	See IVDR 734723
DG Gel Double Pheno	See IVDR 734728

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

Current Issue Date: **2023-05-09**

Starting Validity Date: **2023-05-09**

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

Class D devices	Intended purpose
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	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.
IVP 3001 - In vitro diagnostic devices which require knowledge regarding agglutination tests.	

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

Current Issue Date: **2023-05-09**

Starting Validity Date: **2023-05-09**

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

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
2023-01-18	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
Current	3865550	Supplemented – Addition of DG Gel ABO-CDE, DG Gel Rh Pheno, DG Gel Double Pheno, DG Gel ABO/Rh, DG Gel ABO/Rh (2D), DG Gel Confirm, DG Gel Confirm P, DG Gel Newborn, DG Gel ABO/Rh (2D) (RT), DG Gel (2DVI-), DG Gel Anti-D, DG Gel Rh Pheno + Kell, DG Gel CT

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

Current Issue Date: **2023-05-09**

Starting Validity Date: **2023-05-09**

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

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EU Declaration of Conformity

Manufacturer: Hydrex Diagnostics sp. z o.o.
Aleja Stanów Zjednoczonych 61A
04-028 Warsaw
Poland

Eudamed - ID (SRN): PL-ML-000010271

	Product:	Catalog number:
Product(s)	HX Serowhites 5	HXSB5, HXSB5E
	HX Serowhites 6	HXSB6, HXSB6E
	HX Serowhites 7	HXSB7, HXSB7E
	HX Serowhites 8	HXSB8, HXSB8E
	HX Serowhites 9	HXSB9, HXSB9E
	HX Serowhites 10	HXSB10, HXSB10E
	HX Serowhites 11	HXSB11, HXSB11E
	HX Serowhites 12	HXSB12, HXSB12E

Basic UDI-DI code: 5905669217PLYTY.SEROLOG9L

Risk class: Class A

Classification rule: Rule 5b, Annex VIII of EU Regulation 2017/746

Conformity assessment route: Article 48, Section 10 of EU Regulation 2017/746

This declaration of conformity has been issued under the sole responsibility of the manufacturer, who confirms that the above products comply with the provisions of Regulation (EU) 2017/746 of the European Parliament and of the Council of April 5, 2017, on in vitro diagnostic medical devices.

EU Certificate No.: PN-EN ISO 13485:2016-04 Certificate No. M - 38/10/2025

The product meets the requirements of the following standards:

PN-EN ISO 13485:2016-4	PN-EN ISO 18113-2:2024-12	PN-EN 13641:2006
PN-EN ISO 18113-1:2024-12	PN-EN 23640:2015-10	PN-EN 13612:2006
PN-EN ISO 14971:2020-05/A11:2022-05	PN-EN ISO 15223-1:2022-01	

Tomasz Stasik

Managing Director/Board Member