CERTIFICAT D'EVALUATION UE DE LA DOCUMENTATION TECHNIQUE

Règlement (UE) 2017/746, Annexe IX, chapitre II

EU TECHNICAL DOCUMENTATION ASSESSMENT CERTIFICATE

Regulation (EU) 2017/746, Annex IX, chapter II

Certificat/*Certificate:* N° 39431 rev. 0

Délivré le/*Issued on:* October 19th, 2023

Certificat délivré à/*Certificate issued to:* **DIAGAST**

251 avenue Eugène Avinée, Eurasanté Parc

59120 LOOS FRANCE

SRN: FR-MF-000012310

GMED atteste qu'à l'examen des résultats figurant dans le(s) rapport(s) d'évaluation de la documentation technique référencé(s) P607473 - P607474, le(s) dispositif(s) identifié(s) en addendum de ce certificat est (sont) conforme(s) aux dispositions pertinentes du règlement (UE) 2017/746 pour les produits suivants :

GMED certifies that, on the basis of the results contained in the evaluation report(s) of the technical documentation referenced P607473 - P607474, the device(s) identified in addendum of this certificate complies(comply) with the relevant provisions of the regulation (EU) 2017/746 for the following products:

Réactifs monospécifiques pour les systèmes PK 7300 et PK 7400

Monospecific reagents for systems PK 7300 and PK 7400

Voir détails sur addendum / See addendum for additional information

Aux fins de la mise sur le marché du ou des dispositifs de diagnostic in vitro couverts par ce certificat, un autre certificat délivré conformément aux dispositions du règlement (UE) 2017/746 est requis.

For the purpose of placing on the market the in vitro diagnostic device(s) covered by this certificate, another certificate issued in accordance with the provisions of the regulation (EU) 2017/746 is required.

Début de validité /*Effective date:* October 19th, 2023 (included)

Valable jusqu'au /*Expiry date:* October 18th, 2028 (included)

Le présent certificat est valide pour la ou les configuration(s) du ou des dispositif(s) ayant fait l'objet d'une évaluation satisfaisante de la documentation technique référencée dans le rapport d'évaluation et pour les dispositifs identifiés en addendum du présent certificat. Ce certificat est lié par les conditions du contrat.

This certificate is valid for the configuration (s) of the device (s) for which a satisfying assessment of the technical documentation referenced in the evaluation report has been done and for the devices identified in the addendum to this certificate. This certificate is bound by the conditions of the contract.

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DocuSigned by:

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On behalf of the President

Béatrice LYS

Technical Director

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720 RDM 07/01-99 rev 2

1. **Le cas échéant, le nom et l'adresse du mandataire /** *If applicable, the name and address of the authorised representative:* **NA**
2. **Identification des sites /** *Identification of sites :* **DIAGAST - 251 avenue Eugène Avinée - Eurasanté Parc - 59120 LOOS**
3. **Identification des dispositifs /** *Identification of devices:*

PK 7300 System

Nom du dispositif médical *Medical device name*	IUD-ID de base *Basic UDI-DI*	Référence commerciale *Commercial reference*	Destination* *Intended use*	Code de désignation (type du dispositif) *Designation code (type of the device)*	Classe du DM DIV *IVD MD Class*	Référence aux autres certificats requis pour la mise sur le marché *Reference to other certificates required for placing on the market*
CONTROL PK	3661562DP KBGRXXXXX XXXXX3S	73000	CONTROL PK is an IVDMD intended to be used by healthcare professionals, biologists or lab technicians as negative control to validate the result of blood grouping and phenotyping tests using microplate automated method.	IVR 0101	D	39430
ANTI-A (PK1)	3661562DP KBGRXXXXX XXXXX3S	73001	Anti-A (PK1) is an IVDMD intended to be used by healthcare professionals, biologists or lab technicians for the qualitative detection of red blood cell antigen A (ABO1) in donor blood samples with anticoagulant (EDTA) using a microplate automated method. The determination of the forward (antigen) typing with the reverse (antibody) typing in donors is intended to ensure immunological compatibility and safe transfusion of blood and blood components.	IVR 0101	D	39430
ANTI-B (PK1)	3661562DP KBGRXXXXX XXXXX3S	73002	Anti-B (PK1) is an IVDMD intended to be used by healthcare professionals, biologists or lab technicians for the qualitative detection of red blood cell antigen B (ABO2) in donor blood samples with anticoagulant (EDTA) using a microplate automated method. The determination of the forward (antigen) typing with the reverse (antibody) typing in donors is intended to ensure immunological compatibility and safe transfusion of blood and blood components.	IVR 0101	D	39430
ANTI-AB (PK1)	3661562DP KBGRXXXXX XXXXX3S	73003	Anti-A B (PK1) is an IVDMD intended to be used by healthcare professionals, biologists or lab technicians for the qualitative detection of red blood cell antigen A and B (ABO1and ABO2) in donor blood samples with anticoagulant (EDTA) using a microplate automated method. The determination	IVR 0101	D	39430

DocuSigned by:
On behalf of the President
Béatrice LYS
Technical Director

Nom du dispositif médical *Medical device name*	IUD-ID de base *Basic UDI-DI*	Référence commerciale *Commercial reference*	Destination* *Intended use*	Code de désignation (type du dispositif) *Designation code (type of the device)*	Classe du DM DIV *IVD MD Class*	Référence aux autres certificats requis pour la mise sur le marché *Reference to other certificates required for placing on the market*
			of the forward (antigen) typing with the reverse (antibody) typing in donors is intended to ensure immunological compatibility and safe transfusion of blood and blood components.			
ANTI-D TOTEM PK	3661562DPKBGRXXXXXXXXX3S	73004	ANTI-D TOTEM PK is an IVDMD intended to be used by healthcare professionals, biologists or lab technicians for the qualitative detection of red blood cell antigen D (RH1) in donor blood samples with anticoagulant (EDTA) using a microplate automated method. The phenotyping in donors is intended to ensure immunological compatibility and safe transfusion of blood and blood components.	IVR 0102	D	39430
ANTI-C (PK1)	3661562DPKBGRPHEXXXXXXX5N	73016	Anti-C(PK1) is an IVDMD intended to be used by healthcare professionals, biologists or lab technicians for the qualitative detection of red blood cell antigen C (RH2) in donor blood samples with anticoagulant (EDTA) using a microplate automated method. The phenotyping in donors is intended to ensure immunological compatibility and safe transfusion of blood and blood components.	IVR 0102	D	39430
ANTI-c (PK1)	3661562DPKBGRPHEXXXXXXX5N	73008	Anti-c(PK1) is an IVDMD intended to be used by healthcare professionals, biologists or lab technicians for the qualitative detection of red blood cell antigen c (RH4) in donor blood samples with anticoagulant (EDTA) using a microplate automated method. The phenotyping in donors is intended to ensure immunological compatibility and safe transfusion of blood and blood components.	IVR 0102	D	39430
ANTI-e (PK1)	3661562DPKBGRPHEXXXXXXX5N	73009	Anti-e(PK1) is an IVDMD intended to be used by healthcare professionals, biologists or lab technicians for the qualitative detection of red blood cell antigen e (RH5) in donor blood samples with anticoagulant (EDTA) using a microplate automated method. The phenotyping in donors is intended to ensure immunological compatibility and safe transfusion of blood and blood components.	IVR 0102	D	39430
ANTI-K (PK1)	3661562DPKBGRPHEXXXXXXX5N	73010	Anti-K (PK1) is an IVDMD intended to be used by healthcare professionals, biologists or lab technicians for the qualitative detection of red blood cell antigen K (KEL 1) in donor blood samples with anticoagulant (EDTA) using a microplate automated method. The phenotyping in donors is intended to ensure immunological compatibility and safe transfusion of blood and blood components.	IVR 0103	D	39430
Anti-D (PK1)	3661562DPKBGRDXXXXXXXXXHK	73005	ANTI-D (PK1) is an IVDMD intended to be used by healthcare professionals, biologists or lab technicians for the qualitative detection of red blood cell antigens D (RH1) in donor blood samples with anticoagulant (EDTA) using a microplate automated method. The phenotyping in donors is intended to ensure immunological compatibility and safe transfusion of blood and blood components.	IVR 0102	D	39430

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Béatrice Lys
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On behalf of the President
Béatrice LYS
Technical Director

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Nom du dispositif médical *Medical device name*	IUD-ID de base *Basic UDI-DI*	Référence commerciale *Commercial reference*	Destination* *Intended use*	Code de désignation (type du dispositif) *Designation code (type of the device)*	Classe du DM DIV *IVD MD Class*	Référence aux autres certificats requis pour la mise sur le marché *Reference to other certificates required for placing on the market*
Anti-e (PK)	3661562DP KBGRPHEXX XXXXX5N	73011	Anti-e(PK2) is an IVDMD intended to be used by healthcare professionals, biologists or lab technicians for the qualitative detection of red blood cell antigen e (RH5) in donor blood samples with anticoagulant (EDTA) using a microplate automated method. The phenotyping in donors is intended to ensure immunological compatibility and safe transfusion of blood and blood components.	IVR 0102	D	39430
ANTI-A (PK2)	3661562DP KBGRXXXXX XXXXX3S	73201	Anti-A (PK2) is an IVDMD intended to be used by healthcare professionals, biologists or lab technicians for the qualitative detection of red blood cell antigen A (ABO1) in donor blood samples with anticoagulant (EDTA) using a microplate automated method. The determination of the forward (antigen) typing with the reverse (antibody) typing in donors is intended to ensure immunological compatibility and safe transfusion of blood and blood components.	IVR 0101	D	39430
ANTI-B (PK2)	3661562DP KBGRXXXXX XXXXX3S	73202	Anti-B(PK2) is an IVDMD intended to be used by healthcare professionals, biologists or lab technicians for the qualitative detection of red blood cell antigen B (ABO2) in donor blood samples with anticoagulant (EDTA) using a microplate automated method. The determination of the forward (antigen) typing with the reverse (antibody) typing in donors is intended to ensure immunological compatibility and safe transfusion of blood and blood components.	IVR 0101	D	39430
ANTI-AB (PK2)	3661562DP KBGRXXXXX XXXXX3S	73203	Anti-A B(PK2) is an IVDMD intended to be used by healthcare professionals, biologists or lab technicians for the qualitative detection of red blood cell antigen A and B (ABO1 and ABO2) in donor blood samples with anticoagulant (EDTA) using a microplate automated method. The determination of the forward (antigen) typing with the reverse (antibody) typing in donors is intended to ensure immunological compatibility and safe transfusion of blood and blood components.	IVR 0101	D	39430
ANTI-E (PK2)	3661562DP KBGRPHEXX XXXXX5N	73206	Anti-E(PK2) is an IVDMD intended to be used by healthcare professionals, biologists or lab technicians for the qualitative detection of red blood cell antigen E (RH3) in donor blood samples with anticoagulant (EDTA) using a microplate automated method. The phenotyping in donors is intended to ensure immunological compatibility and safe transfusion of blood and blood	IVR 0102	D	39430
ANTI-c (PK2)	3661562DP KBGRPHEXX XXXXX5N	73207	Anti-c(PK2) is an IVDMD intended to be used by healthcare professionals, biologists or lab technicians for the qualitative detection of red blood cell antigen c (RH4) in donor blood samples with anticoagulant (EDTA) using a microplate automated method. The phenotyping in donors is intended to ensure immunological compatibility and safe transfusion of blood and blood components.	IVR 0102	D	39430

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DocuSigned by:
Béatrice LAS
On behalf of the President
Béatrice LAS
Technical Director

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Nom du dispositif médical *Medical device name*	IUD-ID de base *Basic UDI-DI*	Référence commerciale *Commercial reference*	Destination* *Intended use*	Code de désignation (type du dispositif) *Designation code (type of the device)*	Classe du DM DIV *IVD MD Class*	Référence aux autres certificats requis pour la mise sur le marché *Reference to other certificates required for placing on the market*
ANTI-e (PK2)	3661562DPKBGRPHEXXXXXXX5N	73208	Anti-e(PK2) is an IVDMD intended to be used by healthcare professionals, biologists or lab technicians for the qualitative detection of red blood cell antigen e (RH5) in donor blood samples with anticoagulant (EDTA) using a microplate automated method. The phenotyping in donors is intended to ensure immunological compatibility and safe transfusion of blood and blood components.	IVR 0102	D	39430
ANTI-K (PK2)	3661562DPKBGRPHEXXXXXXX5N	73209	Anti-K (PK2) is an IVDMD intended to be used by healthcare professionals, biologists or lab technicians for the qualitative detection of red blood cell antigen K (KEL 1) in donor blood samples with anticoagulant (EDTA) using a microplate automated method. The phenotyping in donors is intended to ensure immunological compatibility and safe transfusion of blood and blood components.	IVR 0103	D	39430
Anti-D (PK2)	3661562DPKBGRDXXXXXXXXXHK	73204	ANTI-D (PK2) is an IVDMD intended to be used by healthcare professionals, biologists or lab technicians for the qualitative detection of red blood cell antigens D (RH1) in donor blood samples with anticoagulant (EDTA) using a microplate automated method. The phenotyping in donors is intended to ensure immunological compatibility and safe transfusion of blood and blood components.	IVR 0102	D	39430
ANTI-e (PK2)	3661562DPKBGRPHEXXXXXXX5N	73208	Anti-e(PK2) is an IVDMD intended to be used by healthcare professionals, biologists or lab technicians for the qualitative detection of red blood cell antigen e (RH5) in donor blood samples with anticoagulant (EDTA) using a microplate automated method. The phenotyping in donors is intended to ensure immunological compatibility and safe transfusion of blood and blood components.	IVR 0102	D	39430
ANTI-C(PK2)	3661562DPKBGRPHEXXXXXXX5N	73225	Anti-C(PK2) is an IVDMD intended to be used by healthcare professionals, biologists or lab technicians for the qualitative detection of red blood cell antigen C (RH2) in donor blood samples with anticoagulant (EDTA) using a microplate automated method. The phenotyping in donors is intended to ensure immunological compatibility and safe transfusion of blood and blood components.	IVR 0102	D	39430
ANTI-E (PK1)	3661562DPKBGRPHEXXXXXXX5N	73027	Anti-E(PK1) is an IVDMD intended to be used by healthcare professionals, biologists or lab technicians for the qualitative detection of red blood cell antigen E (RH3) in donor blood samples with anticoagulant (EDTA) using a microplate automated method. The phenotyping in donors is intended to ensure immunological compatibility and safe transfusion of blood and blood	IVR 0102	D	39430

*****mentionnée dans la notice d'utilisation / *as included by the manufacturer in the instructions for use*

DocuSigned by:
Béatrice Lys
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On behalf of the President
Béatrice LYS
Technical Director

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PK 7400 System

Nom du dispositif médical *Medical device name*	IUD-ID de base *Basic UDI-DI*	Référence commerciale *Commercial reference*	Destination* *Intended use*	Code de désignation (type du dispositif) *Designation code (type of the device)*	Classe du DM DIV *IVD MD Class*	Référence aux autres certificats requis pour la mise sur le marché *Reference to other certificates required for placing on the market*
Anti-A (PK1)	3661562DPKBGRXXXXXXXXXX3S	B10328	Anti-A (PK1) is an IVDMD intended to be used by healthcare professionals, biologists or lab technicians for the qualitative detection of red blood cell antigen A (ABO1) in donor blood samples with anticoagulant (EDTA) using a microplate automated method. The determination of the forward (antigen) typing with the reverse (antibody) typing in donors is intended to ensure immunological compatibility and safe transfusion of blood and blood components.	IVR 0101	D	39430
Anti-B (PK1)	3661562DPKBGRXXXXXXXXXX3S	B10329	Anti-B (PK1) is an IVDMD intended to be used by healthcare professionals, biologists or lab technicians for the qualitative detection of red blood cell antigen B (ABO1) in donor blood samples with anticoagulant (EDTA) using a microplate automated method. The determination of the forward (antigen) typing with the reverse (antibody) typing in donors is intended to ensure immunological compatibility and safe transfusion of blood and blood components.	IVR 0101	D	39430
Anti-AB (PK1)	3661562DPKBGRXXXXXXXXXX3S	B10330	Anti-AB (PK1) is an IVDMD intended to be used by healthcare professionals, biologists or lab technicians for the qualitative detection of red blood cell antigen A and B (ABO1 and ABO2) in donor blood samples with anticoagulant (EDTA) using a microplate automated method. The determination of the forward (antigen) typing with the reverse (antibody) typing in donors is intended to ensure immunological compatibility and safe transfusion of blood and blood components.	IVR 0101	D	39430
Anti-A (PK2)	3661562DPKBGRXXXXXXXXXX3S	B10331	Anti-A (PK2) is an IVDMD intended to be used by healthcare professionals, biologists or lab technicians for the qualitative detection of red blood cell antigen A (ABO1) in donor blood samples with anticoagulant (EDTA) using a microplate automated method. The determination of the forward (antigen) typing with the reverse (antibody) typing in donors is intended to ensure immunological compatibility and safe transfusion of blood and blood components.	IVR 0101	D	39430
Anti-B (PK2)	3661562DPKBGRXXXXXXXXXX3S	B10332	Anti-B(PK2) is an IVDMD intended to be used by healthcare professionals, biologists or lab technicians for the qualitative detection of red blood cell antigen B (ABO1) in donor blood samples with anticoagulant (EDTA) using a microplate automated method. The determination of the forward	IVR 0101	D	39430

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Béatrice Lys
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On behalf of the President
Béatrice LYS
Technical Director

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Nom du dispositif médical *Medical device name*	IUD-ID de base *Basic UDI-DI*	Référence commerciale *Commercial reference*	Destination* *Intended use*	Code de désignation (type du dispositif) *Designation code (type of the device)*	Classe du DM DIV *IVD MD Class*	Référence aux autres certificats requis pour la mise sur le marché *Reference to other certificates required for placing on the market*
			(antigen) typing with the reverse (antibody) typing in donors is intended to ensure immunological compatibility and safe transfusion of blood and blood components.			
Anti-AB (PK2)	3661562DPKBGRXXXXXXXXX3S	B10333	Anti-AB (PK2) is an IVDMD intended to be used by healthcare professionals, biologists or lab technicians for the qualitative detection of red blood cell antigen A and B (ABO1) in donor blood samples with anticoagulant (EDTA) using a microplate automated method. The determination of the forward (antigen) typing with the reverse (antibody) typing in donors is intended to ensure immunological compatibility and safe transfusion of blood and blood components.	IVR 0101	D	39430
Anti-D (PK2)	3661562DPKBGRDXXXXXXXXXHK	B10336	ANTI-D (PK2) is an IVDMD intended to be used by healthcare professionals, biologists or lab technicians for the qualitative detection of red blood cell antigens D (RH1) in donor blood samples with anticoagulant (EDTA) using a microplate automated method. The phenotyping in donors is intended to ensure immunological compatibility and safe transfusion of blood and blood components.	IVR 0102	D	39430
Anti-C (PK1)	3661562DPKBGRPHEXXXXXXX5N	B10337	Anti-C (PK1) is an IVDMD intended to be used by healthcare professionals, biologists or lab technicians for the qualitative detection of red blood cell antigen C (RH2) in donor blood samples with anticoagulant (EDTA) using a microplate automated method. The phenotyping in donors is intended to ensure immunological compatibility and safe transfusion of blood and blood components.	IVR 0102	D	39430
Anti-E (PK1)	3661562DPKBGRPHEXXXXXXX5N	B10338	Anti-E(PK1) is an IVDMD intended to be used by healthcare professionals, biologists or lab technicians for the qualitative detection of red blood cell antigen E (RH3) in donor blood samples with anticoagulant (EDTA) using a microplate automated method. The phenotyping in donors is intended to ensure immunological compatibility and safe transfusion of blood and blood components.	IVR 0102	D	39430
Anti-c (PK1)	3661562DPKBGRPHEXXXXXXX5N	B10339	Anti-c(PK1) is an IVDMD intended to be used by healthcare professionals, biologists or lab technicians for the qualitative detection of red blood cell antigen c (RH4) in donor blood samples with anticoagulant (EDTA) using a microplate automated method. The phenotyping in donors is intended to ensure immunological compatibility and safe transfusion of blood and blood components.	IVR 0102	D	39430
Anti-e (PK1)	3661562DPKBGRPHEXXXXXXX5N	B10340	Anti-e(PK1) is an IVDMD intended to be used by healthcare professionals, biologists or lab technicians for the qualitative detection of red blood cell antigen e (RH5) in donor blood samples with anticoagulant (EDTA) using a microplate automated method. The phenotyping in donors is intended to ensure immunological compatibility and safe transfusion of blood and blood components.	IVR 0102	D	39430

GMED DocuSigned by: Béatrice LVS

On behalf of the President
Béatrice LVS
Technical Director

Nom du dispositif médical *Medical device name*	IUD-ID de base *Basic UDI-DI*	Référence commerciale *Commercial reference*	Destination* *Intended use*	Code de désignation (type du dispositif) *Designation code (type of the device)*	Classe du DM DIV *IVD MD Class*	Référence aux autres certificats requis pour la mise sur le marché *Reference to other certificates required for placing on the market*
Anti-K (PK1)	3661562DP KBGRPHEXX XXXXX5N	B10341	Anti-K (PK1) is an IVDMD intended to be used by healthcare professionals, biologists or lab technicians for the qualitative detection of red blood cell antigen K (KEL 1) in donor blood samples with anticoagulant (EDTA) using a microplate automated method. The phenotyping in donors is intended to ensure immunological compatibility and safe transfusion of blood and blood components.	IVR 0103	D	39430
Anti-C (PK2)	3661562DP KBGRPHEXX XXXXX5N	B10342	Anti-C(PK2) is an IVDMD intended to be used by healthcare professionals, biologists or lab technicians for the qualitative detection of red blood cell antigen C (RH2) in donor blood samples with anticoagulant (EDTA) using a microplate automated method. The phenotyping in donors is intended to ensure immunological compatibility and safe transfusion of blood and blood components.	IVR 0102	D	39430
Anti-E (PK2)	3661562DP KBGRPHEXX XXXXX5N	B10343	Anti-E(PK2) is an IVDMD intended to be used by healthcare professionals, biologists or lab technicians for the qualitative detection of red blood cell antigen E (RH3) in donor blood samples with anticoagulant (EDTA) using a microplate automated method. The phenotyping in donors is intended to ensure immunological compatibility and safe transfusion of blood and blood components.	IVR 0102	D	39430
Anti-c (PK2)	3661562DP KBGRPHEXX XXXXX5N	B10344	Anti-c(PK2) is an IVDMD intended to be used by healthcare professionals, biologists or lab technicians for the qualitative detection of red blood cell antigen c (RH4) in donor blood samples with anticoagulant (EDTA) using a microplate automated method. The phenotyping in donors is intended to ensure immunological compatibility and safe transfusion of blood and blood components.	IVR 0102	D	39430
Anti-e (PK2)	3661562DP KBGRPHEXX XXXXX5N	B10345	Anti-e(PK2) is an IVDMD intended to be used by healthcare professionals, biologists or lab technicians for the qualitative detection of red blood cell antigen e (RH5) in donor blood samples with anticoagulant (EDTA) using a microplate automated method. The phenotyping in donors is intended to ensure immunological compatibility and safe transfusion of blood and blood components.	IVR 0102	D	39430
Anti-K (PK2)	3661562DP KBGRPHEXX XXXXX5N	B10346	Anti-K (PK2) is an IVDMD intended to be used by healthcare professionals, biologists or lab technicians for the qualitative detection of red blood cell antigen K (KEL 1) in donor blood samples with anticoagulant (EDTA) using a microplate automated method. The phenotyping in donors is intended to ensure immunological compatibility and safe transfusion of blood and blood components.	IVR 0103	D	39430
CONTROL PK	3661562DP KBGRXXXXX XXXXX3S	B10350	CONTROL PK is an IVDMD intended to be used by healthcare professionals, biologists or lab technicians as negative control to validate the result of blood grouping and phenotyping tests using microplate automated method.	IVR 0101	D	39430

DocuSigned by:
On behalf of the President
Beatrice LYS
Technical Director
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Nom du dispositif médical *Medical device name*	IUD-ID de base *Basic UDI-DI*	Référence commerciale *Commercial reference*	Destination* *Intended use*	Code de désignation (type du dispositif) *Designation code (type of the device)*	Classe du DM DIV *IVD MD Class*	Référence aux autres certificats requis pour la mise sur le marché *Reference to other certificates required for placing on the market*
Anti-D (PK)	3661562DP KBGRDXXXX XXXXXHK	B10334	ANTI-D (PK) is an IVDMD intended to be used by healthcare professionals, biologists or lab technicians for the qualitative detection of red blood cell antigens D (RH1) in donor blood samples with anticoagulant (EDTA) using a microplate automated method. The phenotyping in donors is intended to ensure immunological compatibility and safe transfusion of blood and blood components.	IVR 0102	D	39430
Anti-D (PK1)	3661562DP KBGRDXXXX XXXXXHK	B10335	ANTI-D (PK1) is an IVDMD intended to be used by healthcare professionals, biologists or lab technicians for the qualitative detection of red blood cell antigens D (RH1) in donor blood samples with anticoagulant (EDTA) using a microplate automated method. The phenotyping in donors is intended to ensure immunological compatibility and safe transfusion of blood and blood components.	IVR 0102	D	39430

*mentionnée dans la notice d'utilisation / *as included by the manufacturer in the instructions for use*

4. Historique du certificat / *Certificate history:*

Référence au certificat précédent *Reference to the previous certificate*	Date de délivrance *Date of issue*	Modifications apportées *Identification of the changes*
Non applicable/Not Applicable	Non applicable/Not Applicable	Non applicable/Not Applicable

5. Le cas échéant, les informations spécifiques relatives aux limitations de la validité du certificat / *If applicable, specific information relating to the limitations to the validity of the certificate : Non applicable/Not Applicable*

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Béatrice Lys
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On behalf of the President
Béatrice LYS
Technical Director

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6. **Le cas échéant, les informations spécifiques relatives à la surveillance effectuée dans le cadre du maintien du certificat /** *If applicable, specific information relating to the surveillance carried out in the context of maintaining the certificate : Non applicable/Not Applicable*

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Béatrice Lys
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On behalf of the President
Béatrice LYS
Technical Director