



CE mark/*Marquage CE*

EC certificates and declarations of conformity associated with the devices

Attestations et déclarations CE de conformité associées aux dispositifs

* EC certificate EC Annex VII: approval of Production Quality Assurance system/*Attestation CE Annexe VII : approbation du système d'Assurance Qualité de la Production*

** EC certificate Annexe IV: approval full Quality Assurance system/*Attestation CE Annexe IV : approbation du système qualité complet d'Assurance Qualité*

Device/ <i>Dispositif</i>		Category <i>Catégorie</i>	EC certificate - Annex V <i>Attestation CE - Annexe V</i>			EC certificate Annex VII*	EC certificate Annex IV**
Designation/ <i>Désignation</i>	Ref./ <i>Réf.</i>		N°	From/ <i>Du</i>	to/ <i>Au</i>	<i>Attestation CE Annexe VII*</i>	<i>Attestation CE Annexe IV**</i>
QWALYS® 3	90804	Other devices <i>Autres dispositifs</i>	NA	NA	NA	NA	NA
	90854		NA	NA	NA	NA	
IRONMAG	20000		NA	NA	NA	NA	
Anti-S	20505		NA	NA	NA	NA	
Anti-s	20506		NA	NA	NA	NA	
NEG CONTROL	20507		NA	NA	NA	NA	
ANTI-k (KEL2)	20508		NA	NA	NA	NA	
CleanLys	20700		NA	NA	NA	NA	
BROMELINE 1 x 100 ml	69024		NA	NA	NA	NA	
MagLys	69300		NA	NA	NA	NA	
DiluentLys	69301		NA	NA	NA	NA	
I-Mag Diluent	69312		NA	NA	NA	NA	
Mag-Plates	69302		NA	NA	NA	NA	
NanoLys	69305		NA	NA	NA	NA	
ScreenDiluent	69306		NA	NA	NA	NA	
BROMELINE 5 x 100 ml	69860		NA	NA	NA	NA	
DC-Lys	79300	NA	NA	NA	NA		
D-Plates	79851	Other devices <i>Autres dispositifs</i>	NA	NA	NA	NA	NA
Blue Control	79880		NA	NA	NA	NA	
MagneLys	79900		NA	NA	NA	NA	
I-Mag Screen	59857	Annex II list B <i>Annexe II liste B</i>	NA	NA	NA	NA	9577 19/07/19-12/06/21
I-Mag Ident	59859		NA	NA	NA	NA	
ScreenLys Plate	79861		NA	NA	NA	NA	

Device/Dispositif		Category Catégorie	EC certificate - Annex V Attestation CE - Annexe V			EC certificate Annex VII*	EC certificate Annex IV**
Designation/Désignation	Ref./Réf.		N°	From/Du	At/Au	Attestation CE Annexe VII*	Attestation CE Annexe IV**
Anti-D WEAK	20401	Annex II list A Annexe II liste A	21598	06/07/2016	05/07/2021	10492 19/05/20-12/06/21	NA
HEMA CQI	59500	Annex II list A Annexe II liste A	9105	21/07/2015	20/07/2020	10492 19/05/20-12/06/21	NA
HEMALYS 1 A1, B	59659	Annex II list A Annexe II liste A	8428	04/10/2019	03/10/2020	10492 19/05/20-12/06/21	NA
HEMALYS 2 A1, B	59660						
HEMALYS 1 A1, A2, B, O	59661						
HEMALYS 1 A1, B	59663						
DuoLys	79960	Annex II list A Annexe II liste A	8394	19/05/2020	26/05/2024	10492 19/05/20-12/06/21	NA
PhenoLys	79962						
Groupa 2 Lys	79964						
Groupa A1 Lys	79965						
Pheno 1,2 Lys	79966						
Groupa CDE Lys	79968						
Groupa DVI Lys	79969						
DuoLys v2	79070						
PhenoLys v2	79071						
Pheno 1,2 Lys v2	79072						
ABD-Lys	79967						
ABDVI-Lys VI v2	79990	Annex II list A Annexe II liste A	36142	25/10/2019	26/05/2024	10492 19/05/20-12/06/21	NA
ABDVI-Lys v2	79991						
SERA CQI	59502	Annex II list B Annexe II liste B	10499	21/10/2015	20/10/2020	10492 19/05/20-12/06/21	NA
SERA CQI FYA	59503						
Anti-Fya	20501	Annex II list B Annexe II liste B	NA	NA	NA	NA	9577 19/07/19-12/06/21
Anti-Jka	20503		NA	NA	NA	NA	
Anti-Jkb	20504		NA	NA	NA	NA	
ANTI-Fyb (FY2)	20509		NA	NA	NA	NA	
ABS IQC	59507		NA	NA	NA	NA	
HEMASCREEN	59852		NA	NA	NA	NA	
HEMASCREEN Pool	59550		NA	NA	NA	NA	
HEMA-IDENT ^{EXT}	59854		NA	NA	NA	NA	
HEMA-IDENT	59855		NA	NA	NA	NA	
ScreenLys 2	79843		NA	NA	NA	NA	
ScreenLys	79853		NA	NA	NA	NA	
CrossLys	79854		NA	NA	NA	NA	

Device/Dispositif		Category Catégorie	EC certificate - Annex V Attestation CE - Annexe V			EC certificate Annex VII*	EC certificate Annex IV**
Designation/Désignation	Ref./Réf.		N°	From/Du	At/Au	Attestation CE Annexe VII*	Attestation CE Annexe IV**
HEMA CELLS A1, B (PK2)	73040	Annex II list A Annexe II liste A	8615	08/04/2019	22/10/2023	10492 19/05/20-12/06/21	NA
HEMA CELLS A1, B (PK1)	73041						
HEMA CELLS A2 (PK2)	73050						
HEMA CELLS A2 (PK1)	73051						
HEMA CELLS O (PK2)	73060						
HEMA CELLS O (PK1)	73061						
HEMA CELLS A1, B (PK2)	B10903						
HEMA CELLS A1, B (PK1)	B10347						
HEMA CELLS A2 (PK2)	B10904						
HEMA CELLS A2 (PK1)	B10348						
HEMA CELLS O (PK2)	B10905						
HEMA CELLS O (PK1)	B10349						
CONTROL PK	73000						
ANTI-A (PK1)	73001						
ANTI-B (PK1)	73002						
ANTI-AB (PK1)	73003						
ANTI-D TOTEM PK	73004						
ANTI-D (PK1)	73005						
ANTI-A (PK2)	73201						
ANTI-B (PK2)	73202						
ANTI-AB (PK2)	73203						
ANTI-D (PK2)	73204						
CONTROL PK	B10350	Annex II list A Annexe II liste A	9997	08/04/2019	16/10/2023	10492 19/05/20-12/06/21	NA
Anti-A (PK1)	B10328						
Anti-B (PK1)	B10329						
Anti-AB (PK1)	B10330						
Anti-D (PK1)	B10335						
Anti-A (PK2)	B10331						
Anti-B (PK2)	B10332						
Anti-AB (PK2)	B10333						
Anti-D (PK2)	B10336						
Anti-D (PK)	B10334						

Device/Dispositif		Category Catégorie	EC certificate - Annex V Attestation CE - Annexe V			EC certificate Annex VII*	EC certificate Annex IV**
Designation/Désignation	Ref./Réf.		N°	From/Du	At/Au	Attestation CE Annexe VII*	Attestation CE Annexe IV**
ANTI-c (PK1)	73008	Annex II list A Annexe II liste A	10232	13/06/2019	16/10/2023	10492 19/05/20-12/06/21	NA
ANTI-e (PK1)	73009						
ANTI-K (PK1)	73010						
ANTI-e (PK)	73011						
ANTI-C (PK1)	73016						
ANTI-E (PK1)	73027						
ANTI-E (PK2)	73206						
ANTI-c (PK2)	73207						
ANTI-e (PK2)	73208						
ANTI-K (PK2)	73209						
ANTI-C (PK2)	73225						
ANTI-Fya (FY1) PK	73020	Annex II list B Annexe II liste B	NA	NA	NA	NA	9577 19/07/19-12/06/21
ANTI-Fyb (FY2) PK	73021		NA	NA	NA	NA	
ANTI-Jka (JK1) PK	73022		NA	NA	NA	NA	
ANTI-Jkb (JK2) PK	73023		NA	NA	NA	NA	
NEG CONTROL PK	73026		NA	NA	NA	NA	
AGH ANTI-IgG PK	73028		NA	NA	NA	NA	
ANTI-S (MNS3) PK	73024	Other devices Autres dispositifs	NA	NA	NA	NA	NA
ANTI-s (MNS4) PK	73025		NA	NA	NA	NA	
LISS PK	73029		NA	NA	NA	NA	
BROMELINE PK	73300		NA	NA	NA	NA	
PAD Buffer	40100		NA	NA	NA	NA	
PAD Buffer 500	40104		NA	NA	NA	NA	
AB PAD	40101	Annex II list A Annexe II liste A	33642	04/05/2020	26/11/2022	10492 19/05/20-12/06/21	NA
ABD PAD	40102						
HEMATEST A1, B	58950	Annex II list A Annexe II liste A	9235	09/09/2018	08/09/2023	10492 19/05/20-12/06/21	NA
HEMATEST A1, A2, B, O	51999						
ANTI-A (ABO1)	5 x 10 ml	Annex II list A Annexe II liste A	8383	01/10/2018	30/09/2023	10492 19/05/20-12/06/21	NA
ANTI-B (ABO2)	5 x 10 ml						
ANTI-A,B (ABO3)	5 x 10 ml						
ANTI-A (ABO1)	100 x 10 ml						
ANTI-B (ABO2)	100 x 10 ml						
ANTI-A,B (ABO3)	100 x 10 ml						
ANTI-D (RH1) IgM I	100 x 10 ml						
ANTI-D (RH1) TOTEM	100 x 10 ml						
NEG CONTROL	100 x 10 ml						
GROUPAKIT	70888						
ANTI-D (RH1) IgM I	5 x 10 ml						
ANTI-D (RH1) IgM II	5 x 10 ml						
ANTI-D (RH1) TOTEM	5 x 10 ml						
ANTI-D (RH1) IgG	5 x 10 ml						
ANTI-DCE (RH1,2,3)	5 x 5 ml						
NEG CONTROL	5 x 10 ml						

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ANTI-c (RH4)	74011	Annex II list A Annexe II liste A	9522	07/07/2018	06/07/2023	10492 19/05/20-12/06/21	NA
ANTI-C (RH2)	74221						
ANTI-E (RH3)	74311						
ANTI-e (RH5)	74611						
ANTI-K (KEL1)	74711						
PHENOKIT	74911						
SAFETY TEST ABO	79069	Annex II list A Annexe II liste A	24618	13/12/2018	12/12/2022	10492 19/05/20-12/06/21	NA
SAFETY CARD AB	79074						
SAFETY CARD AB	79075						
SAFETY CARD AB	79076						
ABTest Card	79070	Annex II list A Annexe II liste A	32801	26/02/2020	25/02/2021	10492 19/05/20-12/06/21	NA
ABTest MULTI	79080	Annex II list A Annexe II liste A	32800	04/10/2018	01/03/2021	10492 19/05/20-12/06/21	NA
AGH MAESTRIA C3D	76118	Annex II list B Annexe II liste B	9280	22/01/2019	02/12/2023	10492 19/05/20-12/06/21	NA
AGH MAESTRIA IGG	76218						
AGH MAESTRIA IGG + C3D	76318						
ANTI-Jka (JK1)	78003	Annex II list B Annexe II liste B	NA	NA	NA	NA	9577 19/07/19-12/06/21
ANTI-Jkb (JK2)	78004		NA	NA	NA	NA	
ANTI-Fya (FY1)	78014		NA	NA	NA	NA	
ANTI-Fyb (FY2)	78015		NA	NA	NA	NA	
ANTI-M (MNS1)	78005		NA	NA	NA	NA	
ANTI-N (MNS2)	78006	Other devices Autres dispositifs	NA	NA	NA	NA	NA
ANTI-S (MNS3)	78007		NA	NA	NA	NA	
LISS	69013		NA	NA	NA	NA	
PALERM	69015		NA	NA	NA	NA	
ANTI-s (MNS4)	78008		NA	NA	NA	NA	
ANTI-Lea (LE1)	78009		NA	NA	NA	NA	
ANTI-Leb (LE2)	78010		NA	NA	NA	NA	
ANTI-P1	78011		NA	NA	NA	NA	
ANTI-Cw (RH8)	78013		NA	NA	NA	NA	
ANTI-k (KEL2)	78016		NA	NA	NA	NA	

NA : not applicable/non applicable

Comments

- All our devices of annex II list A depend on the annexes V + VII (Directive 98/79/EC).
- Certain devices of annex II list B depend on the annexes V + VII (eg: SERA CQI), others (eg: ScreenLys) depend on the annex IV (Directive 98/79/EC).
- The other devices depend on annex III (Directive 98/79/EC).

Commentaires

- Tous nos dispositifs de l'annexe II liste A dépendent des annexes V + VII (Directive 98/79/CE).
- Certains dispositifs de l'annexe II liste B dépendent des annexes V + VII (ex. : SERA CQI), d'autres (ex. : ScreenLys) dépendent de l'annexe IV (Directive 98/79/CE).
- Les autres dispositifs dépendent de l'annexe III (Directive 98/79/CE).