



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>	At/ <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	
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	
Anti-D WEAK	20401	Annex II list A <i>Annexe II liste A</i>	21598	06/07/2016	05/07/2021	10492 05/06/18-12/06/21	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 CQI	59500	Annex II list A Annexe II liste A	9105	21/07/2015	20/07/2020	10492 05/06/18-12/06/21	NA
HEMALYS 1 A1, B	59659	Annex II list A Annexe II liste A	8428	23/03/2017	03/10/2019	10492 05/06/18-12/06/21	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	22/10/2014	21/10/2019	10492 05/06/18-12/06/21	NA
PhenoLys	79962						
Groupa 2 Lys	79964						
Groupa A1 Lys	79965						
Pheno 1,2 Lys	79966						
Groupa CDE Lys	79968						
Groupa DVI Lys	79969						
ABD-Lys	79967	Annex II list A Annexe II liste A	8248	14/03/2017	13/03/2022	10492 05/06/18-12/06/21	NA
SERA CQI	59502	Annex II list B Annexe II liste B	10499	21/10/2015	20/10/2020	10492 05/06/18-12/06/21	NA
SERA CQI FYA	59503						
Anti-Fya	20501	Annex II list B Annexe II liste B	NA	NA	NA	NA	9577 05/06/18-12/06/21
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	

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HEMA CELLS A1, B PK	59029	Annex II list A Annexe II liste A	8615	23/10/2013	22/10/2018	10492 05/06/18-12/06/21	NA
HEMA CELLS A1, A2, B, O (PK2)	59030						
HEMA CELLS A1, A2, B, O (PK1)	59031						
HEMA CELLS A1, B (PK2)	73040						
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						
CONTROL PK	72000	Annex II list A Annexe II liste A	9997	17/10/2013	16/10/2018	10492 05/06/18-12/06/21	NA
ANTI-A (PK1)	72001						
ANTI-B (PK1)	72002						
ANTI-AB (PK1)	72003						
ANTI-D TOTEM PK	72004						
ANTI-D (PK1)	72005						
ANTI-A (PK2)	72101						
ANTI-B (PK2)	72102						
ANTI-AB (PK2)	72103						
ANTI-D (PK2)	72104						
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						

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ANTI-c (PK1)	73008	Annex II list A Annexe II liste A	10232	02/08/2017	16/10/2018	10492 05/06/18-12/06/21	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 05/06/18-12/06/21
ANTI-Fyb (FY2) PK	73021						
ANTI-Jka (JK1) PK	73022						
ANTI-Jkb (JK2) PK	73023						
NEG CONTROL PK	73026						
AGH ANTI-IgG PK	73028						
ANTI-S (MNS3) PK	73024		NA	NA	NA	NA	
ANTI-s (MNS4) PK	73025						
LISS PK	73029						
BROMELINE PK	73300						
PAD Buffer	40100						
PAD Buffer 500	40104						
AB PAD	40101						
ABD PAD	40102	Annex II list A Annexe II liste A	33642	27/11/2017	26/11/2022	10492 05/06/18-12/06/21	NA
HEMATEST A1, B	58950	Annex II list A Annexe II liste A	9235	31/07/2015	08/09/2018	10492 05/06/18-12/06/21	
HEMATEST A1, A2, B, O	51999	Annex II list A Annexe II liste A					

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-A (ABO1)	5 x 10 ml	70501	8383	27/08/2015	30/09/2018	10492 05/06/18-12/06/21	NA
ANTI-B (ABO2)	5 x 10 ml	70502					
ANTI-A,B (ABO3)	5 x 10 ml	70503					
ANTI-A (ABO1)	100 x 10 ml	70540					
ANTI-B (ABO2)	100 x 10 ml	70541					
ANTI-A,B (ABO3)	100 x 10 ml	70542					
ANTI-D (RH1) IgM I	100 x 10 ml	70543					
ANTI-D (RH1) TOTEM	100 x 10 ml	70544					
NEG CONTROL	100 x 10 ml	70545					
GROUPAKIT		70888					
ANTI-D (RH1) IgM I	5 x 10 ml	71000					
ANTI-D (RH1) IgM II	5 x 10 ml	71005					
ANTI-D (RH1) TOTEM	5 x 10 ml	71010					
ANTI-D (RH1) IgG	5 x 10 ml	71020					
ANTI-DCE (RH1,2,3)	5 x 5 ml	74111					
NEG CONTROL	5 x 10 ml	79000					
ANTI-c (RH4)		74011	9522	07/07/2018	06/07/2023	10492 05/06/18-12/06/21	NA
ANTI-C (RH2)		74221					
ANTI-E (RH3)		74311					
ANTI-e (RH5)		74611					
ANTI-K (KEL1)		74711					
PHENOKIT		74911					
SAFETY TEST ABO		79069	24618	13/12/2017	12/12/2018	10492 05/06/18-12/06/21	NA
SAFETY CARD AB		79074					
SAFETY CARD AB		79075					
SAFETY CARD AB		79076					
ABTest Card		79070	32801	10/04/2018	25/02/2020	10492 05/06/18-12/06/21	NA
ABTest MULTI		79080	32800	27/03/2017	01/03/2021	10492 05/06/18-12/06/21	NA

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AGH MAESTRIA C3D	76118	Annex II list B <i>Annexe II liste B</i>	9280	31/07/2015	02/12/2018	10492 05/06/18-12/06/21	NA
AGH MAESTRIA IGG	76218						
AGH MAESTRIA IGG + C3D	76318						
ANTI-Jka (JK1)	78003	Annex II list B <i>Annexe II liste B</i>	NA	NA	NA	NA	9577 05/06/18-12/06/21
ANTI-Jkb (JK2)	78004		NA	NA	NA	NA	
ANTI-Fya (FY1)	78014		NA	NA	NA	NA	
ANTI-Fyb (FY2)	78112		NA	NA	NA	NA	
ANTI-Fyb (FY2)	78015		NA	NA	NA	NA	
POLY CONTROL	78200		NA	NA	NA	NA	
ANTI-M (MNS1)	78005		NA	NA	NA	NA	
ANTI-N (MNS2)	78006	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	Other devices <i>Autres dispositifs</i>	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		
SAFETY PACK	79055	NA	NA	NA	NA		
Anti-A Life	80700	Annex II list A <i>Annexe II liste A</i>	8628	26/11/2013	07/10/2018	10492 05/06/18-12/06/21	NA
Anti-A Life up	80701						
Anti-B Life	80702						
Anti-B Life up	80703						
Anti-A,B Life	80704						
Anti-D IgG-IgM Life	80705						
Anti-D IgM Life	80706						
Anti-DCE Life	80711						

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Designation/Désignation	Ref./Réf.		N°	From/Du	At/Au	Attestation CE Annexe VII*	Attestation CE Annexe IV**
Anti-C Life	80707	Annex II list A Annexe II liste A	8712	08/10/2013	07/10/2018	10492 05/06/18-12/06/21	NA
Anti-c Life	80708						
Anti-E Life	80709						
Anti-e Life	80710						
Anti-K Life	80712						
Life Control	80713						
HemaLife A1, A2, B, O	80714	Annex II list A Annexe II liste A	20293	17/12/2015	16/12/2020	10492 05/06/18-12/06/21	NA
BromeLife	80715	Other devices Autres dispositifs	NA	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).