



## 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 22/10/18-12/06/21	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 22/10/18-12/06/21	NA
HEMALYS 1 A1, B	59659	Annex II list A Annexe II liste A	8428	23/03/2017	03/10/2019	10492 22/10/18-12/06/21	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 22/10/18-12/06/21	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 22/10/18-12/06/21	NA
SERA CQI	59502	Annex II list B Annexe II liste B	10499	21/10/2015	20/10/2020	10492 22/10/18-12/06/21	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 <sup>EXT</sup>	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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Designation/Désignation	Ref./Réf.		N°	From/Du	At/Au	Attestation CE Annexe VII*	Attestation CE Annexe IV**
HEMA CELLS A1, B PK	59029	Annex II list A Annexe II liste A	8615	23/10/2018	22/10/2023	10492 22/10/18-12/06/21	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	17/10/2018	16/10/2019	10492 22/10/18-12/06/21	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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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	17/10/2018	18/10/2019	10492 22/10/18-12/06/21	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		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	27/11/2017	26/11/2022	10492 22/10/18-12/06/21	NA	
ABD PAD	40102							
HEMATEST A1, B	58950	Annex II list A Annexe II liste A	9235	09/09/2018	08/09/2023	10492 22/10/18-12/06/21	NA	
HEMATEST A1, A2, B, O	51999							

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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	01/10/2018	30/09/2023	10492 22/10/18-12/06/21	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 22/10/18-12/06/21	NA
ANTI-C (RH2)		74221					
ANTI-E (RH3)		74311					
ANTI-e (RH5)		74611					
ANTI-K (KEL1)		74711					
PHENOKIT		74911					
SAFETY TEST ABO		79069	24618	13/12/2018	12/12/2022	10492 22/10/18-12/06/21	NA
SAFETY CARD AB		79074					
SAFETY CARD AB		79075					
SAFETY CARD AB		79076					
ABTest Card		79070	32801	10/04/2018	25/02/2020	10492 22/10/18-12/06/21	NA
ABTest MULTI		79080	32800	04/10/2018	01/03/2021	10492 22/10/18-12/06/21	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 22/10/18-12/06/21	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 22/10/18-12/06/21	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 22/10/18-12/06/21	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 22/10/18-12/06/21	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).