



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/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**
QWALYS® 3	90804	Other devices <i>Autres dispositifs</i>	NA	NA	NA	NA	NA
	90854		NA	NA	NA	NA	
QWALYS® 2 up	90806		NA	NA	NA	NA	
	90856		NA	NA	NA	NA	
QWALYS Connect	90860		NA	NA	NA	NA	
FREELYS® Nano	90751		NA	NA	NA	NA	
FREELYS® Reader	90651		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	
ScreenDiluent 2	69304		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		

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Designation/Désignation	Ref./Réf.		N°	From/Du	At/Au	Attestation CE Annexe VII*	Attestation CE Annexe IV**
D-Plates	79851	Other devices Autres dispositifs	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 Annexe II liste A	21598	06/07/2016	05/07/2021	10492 27/11/17 - 12/06/18	NA
HEMA CQI	59500	Annex II list A Annexe II liste A	9105	21/07/2015	20/07/2020	10492 27/11/17 - 12/06/18	NA
HEMALYS 1 A1, B	59659	Annex II list A Annexe II liste A	8428	23/03/2017	03/10/2019	10492 27/11/17 - 12/06/18	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 27/11/17 - 12/06/18	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 27/11/17 - 12/06/18	NA
SERA CQI	59502	Annex II list B Annexe II liste B	10499	21/10/2015	20/10/2020	10492 27/11/17 - 12/06/18	NA
SERA CQI FYA	59503						
Anti-Fya	20501	Annex II list B Annexe II liste B	NA	NA	NA	NA	9577 13/06/15 – 12/06/18
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	

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Designation/Désignation	Ref./Réf.		N°	From/Du	At/Au	Attestation CE Annexe VII*	Attestation CE Annexe IV**						
CrossLys	79854		NA	NA	NA	NA							
HEMA CELLS A1, B PK	59029	Annex II list A Annexe II liste A	8615	23/10/2013	22/10/2018	10492 27/11/17 - 12/06/18	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 27/11/17 - 12/06/18	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												
ANTI-c (PK1)	72008												
ANTI-e (PK1)	72009												
ANTI-K (PK1)	72010												

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)	72016	Annex II list A Annexe II liste A	10232	17/10/2013	16/10/2018	10492 27/11/17 - 12/06/18	NA
ANTI-E (PK1)	72017						
ANTI-E (PK2)	72106						
ANTI-c (PK2)	72107						
ANTI-e (PK2)	72108						
ANTI-K (PK2)	72109						
ANTI-C (PK2)	72115						
ANTI-c (PK1)	73008						
ANTI-e (PK1)	73009						
ANTI-K (PK1)	73010						
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 13/06/15 – 12/06/18
ANTI-Fyb (FY2) PK	73021						
ANTI-Jka (JK1) PK	73022						
ANTI-Jkb (JK2) PK	73023						
NEG CONTROL PK	73026						
AGH ANTI-IgG PK	73028						
BROMELINE PK	72250	Other devices Autres dispositifs	NA	NA	NA	NA	NA
ANTI-S (MNS3) PK	73024						
ANTI-s (MNS4) PK	73025						
LISS PK	73029						
BROMELINE PK	73300						
PAD Buffer	40100						
PAD Buffer 500	40104						
AB PAD	40101	Annex II list A Annexe II liste A	33642	27/11/2017	26/11/2022	10492 27/11/17 - 12/06/18	NA
ABD PAD	40102						
HEMATEST A1, B	58950	Annex II list A	9235	31/07/2015	08/09/2018	10492	NA

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Designation/Désignation	Ref./Réf.		N°	From/Du	At/Au	Attestation CE Annexe VII*	Attestation CE Annexe IV**
HEMATEST A1, A2, B, O	51999	Annexe II liste A	9289	31/07/2015	08/09/2018	27/11/17 - 12/06/18	
ANTI-A (ABO1) 5 x 10 ml	70501	Annex II list A Annexe II liste A	8383	27/08/2015	30/09/2018	10492 27/11/17 - 12/06/18	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	Annex II list A Annexe II liste A	9522	31/07/2015	06/07/2018	10492 27/11/17 - 12/06/18	NA
ANTI-C (RH2)	74221						
ANTI-E (RH3)	74311						
ANTI-e (RH5)	74611						
ANTI-K (KEL1)	74711						
PHENOKIT	74911	Annex II list A Annexe II liste A	24618	13/12/2017	12/12/2018	10492 27/11/17 - 12/06/18	NA
SAFETY TEST ABO	79069						
SAFETY CARD AB	79074						
SAFETY CARD AB	79075						
SAFETY CARD AB	79076	Annex II list A Annexe II liste A	32801	27/03/2017	25/02/2020	10492 27/11/17 - 12/06/18	NA
ABTest Card	79070						
ABTest MULTI	79080	Annex II list A Annexe II liste A	32800	27/03/2017	01/03/2021	10492 27/11/17 - 12/06/18	NA
AGH MAESTRIA C3D	76118	Annex II list B Annexe II liste B	9280	31/07/2015	02/12/2018	10492 27/11/17 - 12/06/18	NA
AGH MAESTRIA IGG	76218						

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AGH MAESTRIA IGG + C3D	76318	Annex II list B Annexe II liste B				27/11/17 - 12/06/18			
ANTI-Jka (JK1)	78003	Annex II list B Annexe II liste B	NA	NA	NA	NA	9577 13/06/15 – 12/06/18		
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	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			
SAFETY PACK	79055		NA	NA	NA	NA			
SYPAL CB	69110		Other devices Autres dispositifs	NA	NA	NA		NA	NA
SEROPOS	69125		NA	NA	NA	NA		NA	
Anti-A Life	80700	Annex II list A Annexe II liste A	8628	26/11/2013	07/10/2018	10492 27/11/17 - 12/06/18	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								
Anti-C Life	80707	Annex II list A Annexe II liste A	8712	08/10/2013	07/10/2018	10492 27/11/17 - 12/06/18	NA		
Anti-c Life	80708								
Anti-E Life	80709								
Anti-e Life	80710								

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Designation/Désignation	Ref./Réf.		N°	From/Du	At/Au	Attestation CE Annexe VII*	Attestation CE Annexe IV**
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 27/11/17 - 12/06/18	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).