



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	
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		

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**
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	06/07/2011	05/07/2016	10492 13/06/15 - 12/06/18	NA
HEMA CQI	59500	Annex II list A Annexe II liste A	9105	21/07/2015	20/07/2020	10492 13/06/15 - 12/06/18	NA
HEMALYS 1 A1, B	59659	Annex II list A Annexe II liste A	8428	04/10/2014	03/09/2019	10492 13/06/15 - 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 13/06/15 - 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	14/03/2012	13/03/2017	10492 13/06/15 - 12/06/18	NA
SERA CQI	59502	Annex II list B Annexe II liste B	10499	21/10/2015	20/10/2020	10492 13/06/15 - 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-Fyb	20502						
Anti-Jka	20503						
Anti-Jkb	20504						
ANTI-Fyb (FY2)	20509						
ABS IQC	59507						
HEMASCREEN	59852						
HEMASCREEN Pool	59550						
HEMA-IDENT ^{EXT}	59854						
HEMA-IDENT	59855						
ScreenLys 2	79843						
ScreenLys	79853						
CrossLys	79854						

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**
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HEMA CELLS A1, B PK	59029	Annex II list A <i>Annexe II liste A</i>	8615	23/10/2013	22/10/2018	10492 13/06/15 - 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						
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						

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>	
ANTI-c (PK1)	72008	Annex II list A <i>Annexe II liste A</i>	10232	17/10/2013	16/10/2018	10492 13/06/15 - 12/06/18	NA	
ANTI-e (PK1)	72009							
ANTI-K (PK1)	72010							
ANTI-C (PK1)	72016							
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 <i>Annexe II liste B</i>	NA	NA	NA	9577 13/06/15 – 12/06/18		
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
BROMELINE PK	72250	Other devices <i>Autres dispositifs</i>	NA	NA	NA	NA	NA	
ANTI-S (MNS3) PK	73024		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			
HEMATEST A1, B	58950	Annex II list A <i>Annexe II liste A</i>	9235	31/07/2015	08/09/2018	10492 13/06/15 - 12/06/18	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	Annex II list A Annexe II liste A	8383	27/08/2015	30/09/2018	10492 13/06/15 - 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						
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	13/12/2012	12/12/2017	10492 13/06/15 - 12/06/18	NA
SAFETY CARD AB		79074						
SAFETY CARD AB		79075						
SAFETY CARD AB		79076						
AGH MAESTRIA C3D		76118	Annex II list B Annexe II liste B	9280	31/07/2015	02/12/2018	10492 13/06/15 - 12/06/18	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 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						
POLY CONTROL		78200		NA	NA	NA	NA	

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ANTI-M (MNS1)	78005	Other devices <i>Autres dispositifs</i>	NA	NA	NA	NA	NA
ANTI-N (MNS2)	78006		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 <i>Autres dispositifs</i>	NA	NA	NA	
SEROPOS	69125	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 13/06/15 - 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 <i>Annexe II liste A</i>	8712	08/10/2013	07/10/2018	10492 13/06/15 - 12/06/18	NA
Anti-c Life	80708						
Anti-E Life	80709						
Anti-e Life	80710						
Anti-K Life	80712						
Life Control	80713	Annex II list A <i>Annexe II liste A</i>	20293	17/12/2010	16/12/2015	10492 13/06/15 - 12/06/18	NA
HemaLife A1, A2, B, O	80714						
BromeLife	80715	Other devices <i>Autres dispositifs</i>	NA	NA	NA	NA	NA

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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).