



DECLARATION OF CONFORMITY

Manufacturer	Fabricante	CHROMagar
Fabricant	Fabricante	4, place du 18 Juin 1940
Hersteller	Produttore	F-75006, Paris, FRANCE

CHROMagar™ hereby declares that products concerned by European Union directive IVD/98/79/EC (cf. annex 1) conform to the European Union directive and standards referred in this norm.

CHROMagar™ déclare par la présente que les produits concernés par la directive Européenne IVD/98/79/CE (cf. annexe 1) sont conformes aux directives et normes européennes identifiées dans cette norme.

CHROMagar™ bestätigt hiermit, dass die Produkte allen Anforderungen der Richtlinie 98/79/EG des Europäischen Parlamentes über In-vitro-Diagnostika entspricht (cf. anlage 1).

CHROMagar™ dichiara con la presente che i prodotti ai quali si riferisce la direttiva Europea IVD/98/79/CE (cf. annesso 1) sono conformi alle direttive e norme europee identificate in questa norma.

Por la presente, CHROMagar™ declara que sus productos (cf. anexo 1) son conforme las directivas y standards de la norma IVD/98/79/CE de la Union Europea.

CHROMagar™ por meio desta declara que os produtos envolvidos na diretriz da União Européia IVD/98/79/CE (cf. anexo 1) estão de acordo com os padrões e diretrizes referentes a norma acima citada.

EU Directive	Direttiva Europea	IVD/98/79/CE
Directive Européenne	Directiva UE	(27/10/1998)
EU Richtlinie	Directiva UE	annex I & III

Standards	Norma(e)	EN ISO 18113-2:2012
		EN ISO 18113-1:2012
Normes	Estandar(es)	ISO 13485:2016
Normen und Richtlinien	Padrao	EN ISO 15223-1:2017
		EN ISO 15223-2:2010
		EN ISO 14971:2013

Classification	Classificazione	EDMA code: 1401
Classification	Clasificación	GMDN code: 39961
Klassifizierung	Classificação	Risk Class A IVD
		According to Global Harmonization
		Task Force GHTF/SG1/N045:2008

16 September 2020, Céline Binet
Quality Manager

C. BINET
Quality Manager

Quality Control Department

CHROMagar
4, Place du 18 Juin 1940
75006 PARIS - FRANCE



DECLARATION OF CONFORMITY (Annex 1)

Products	Article number	Labels codes	
		BASE	SUPPLEMENTS
CHROMagar™ Candida	CA223-10KG	CA223-10KG	--
	CA223-25	CA223-25	
	CA222	CA222	
CHROMagar™ Orientation	RT413-10KG	RT413-10KG	--
	RT413-25	RT413-25	
	RT412	RT412	
CHROMagar™ MH Orientation	MH482	MH482(B)	MH482(S)
	MH483-25	MH483-25(B)	5 x MH482(S)
CHROMagar™ Staph aureus	TA672	TA672	
CHROMagar™ MRSA	MR502	MR502	SU620
CHROMagar™ MRSA (same product but different preparation steps)	MR533-10KG	MR533-10KG(A)	MR513-125(B)
			MR513-125(C)
			SU625
CHROMagar™ Salmonella	SA133-25	SA133-25	--
	SA132	SA132	
CHROMagar™ VRE	VR953-10KG	VR953-10KG(B)	VR953-150(S)
	VR952	VR952(B)	VR952(S)
CHROMagar™ VRE blue	VR862	VR862(B)	VR862(S)
	VR863-25	VR863-25(B)	VR863-25(S)
CHROMagar™ StrepB	SB283-25	SB283-25(B)	SB283-25(S1)
			SB283-25(S2)
	SB282	SB282(B)	SB282(S1)
			SB282(S2)
CHROMagar™ ESBL	ESRT3-25	RT413-25	ES373-25
	ESRT2	RT412	ES372
CHROMagar™ KPC	KPRT3-25	RT413-25	KP103-25
	KPRT2	RT412	KP102
CHROMagar™ Acinetobacter	AC092	AC092(B)	AC092(S)
CHROMagar™ MDR Supplement (to order with CHROMagar™ Acinetobacter)	CR102	--	CR102
CHROMagar™ STEC	ST162	ST162(B)	ST162(S) (5 vials)
CHROMagar™ Y.enterocolitica	YE492	YE492(B)	YE492(S)
CHROMagar™ C3G ^R	CGRT2	RT412	CG632
	CGRT3-25	RT413-25	CG633-25

CHROMagar™

The Chromogenic Media Pioneer

CHROMagar™ Malassezia	MZ283-25	MZ283-25	--
	MZ282	MZ282	
CHROMagar™ C.difficile	CD122	CD122(B)	CD122(S)
CHROMagar™ mSuperCARBA™	SC173-25	SC173-25(B)	SC173-25(S1)
			SC173-25(S2)
	SC172	SC172(B)	SC172(S1)
			SC172(S2)
CHROMagar™ Campylobacter	CP572	CP572(B)	CP572(S)
	CP573-25	CP573-25(B)	CP573-25(S)
LIM RambaQUICK™ StrepB	LB082	LB082(B)	LB082(S)
CHROMagar™ COL-APSE	CO262	CO262(B)	CO262(S)
CHROMagar™ StrepA	SP373-10KG	SP373-10KG(B)	SP373-10KG(S1)
			SP373-10KG(S2)
	SP373-25	SP373-25(B)	SP373-25(S1)
			SP373-25(S2)
	SP372	SP372(B)	SP372(S1)
			SP372(S2)
CHROMagar™ Serratia	SM302	SM302(B)	SM302(S)
CHROMagar™ Candida Plus	CA243-10KG	CA243-10KG	--
	CA243-25	CA243-25	
	CA242	CA242	
CHROMagar™ LIN-R	LN762	LN762(B)	LN762(S)

16 September 2020, Céline Binet


C. BINET
Quality Manager

Quality Control Department

CHROMagar
4, Place du 18 Juin 1940
75006 PARIS - FRANCE