



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 18113-2:2011
Normes	Estandar(es)	EN ISO 18113-1:2011
Normen und Richtlinien	Padrao	ISO 13485:2003
		EN ISO 15223-1:2017
		EN ISO 15223-2:2010
		EN ISO 14971:2012

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

6 October 2017, Céline Binet
Director of Quality Assurance

C. BINET
Quality Manager

Quality Control Department

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

CHROMagar

The Chromogenic Media Pioneer



DECLARATION OF CONFORMITY (Annex 1)

Products /	Article number
CHROMagar™ Candida	CA220/CA222/CA223
<i>4 dol.</i> CHROMagar™ Orientation	RT410/RT412/RT413
CHROMagar™ Staph aureus	TA670/TA672
CHROMagar™ MRSA	MR500/MR502/MR533/SU620/SU625
CHROMagar™ O157	EE220/EE222/EE223
CHROMagar™ Salmonella	SA130/SA132/SA133
CHROMagar™ Salmonella Plus	SA162/ SA163
Rambach™ Agar	RR702/RR703
CHROMagar™ Listeria	LM850/ LM851/LM852/LM853
CHROMagar™ Identification Listeria	LK970
CHROMagar™ VRE	VR952/VR953
CHROMagar™ StrepB	SB282/SB283
CHROMagar™ ESBL	ES372/ES373
CHROMagar™ KPC	KP102/KP103
CHROMagar™ Acinetobacter	AC092/AC093
CHROMagar™ STEC	ST160/ST162/ST163
CHROMagar™ Y.enterocolitica	YE492
CHROMagar™ MH Orientation	MH482/MH483
CHROMagar™ C.difficile	CD122
CHROMagar™ C3G ^R	CG632/ CG633
CHROMagar™ Vibrio	VB910/VB912/VB913
<i>5 dal.</i> CHROMagar™ mSuperCARBA™	SC172/SC173
CHROMagar™ Campylobacter	CP572/CP573
CHROMagar™ Malassezia	MZ282/MZ283
LIM RambaQUICK™ StrepB	LB082

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