



## 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   |
| Normes                 | Estandar(es) | EN980:2008  |
| Normen und Richtlinien | Padrao       | EN ISO 15223-1:2012 &<br>EN ISO 15223-2:2010<br>ISO14971:2013 |

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

18 April 2016, 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                      |
|---|-------------------------------------|
| <b>CHROMagar™ Candida</b>                 | CA220/CA222/CA223                   |
| <b>CHROMagar™ Orientation</b>             | RT410/RT412/RT413                   |
| <b>CHROMagar™ Staph aureus</b>            | TA670/TA672/TA652                   |
| <b>CHROMagar™ MRSA</b>                    | MR500/MR502/MR513/MR533/SU620/SU625 |
| <b>CHROMagar™ O157</b>                    | EE220/EE222/EE223                   |
| <b>CHROMagar™ Salmonella</b>              | SA130/SA132/SA133                   |
| <b>CHROMagar™ Salmonella Plus</b>         | SA162/ SA163                        |
| <b>Rambach™ Agar</b>                      | RR702/RR703                         |
| <b>CHROMagar™ Listeria</b>                | LM850/ LM851/LM852/LM853            |
| <b>CHROMagar™ Identification Listeria</b> | LK970                               |
| <b>CHROMagar™ VRE</b>                     | VR952/VR953                         |
| <b>CHROMagar™ StrepB</b>                  | SB282/SB283                         |
| <b>CHROMagar™ ESBL</b>                    | ES372/ES373                         |
| <b>CHROMagar™ KPC</b>                     | KP102/KP103                         |
| <b>CHROMagar™ Acinetobacter</b>           | AC092/AC093                         |
| <b>CHROMagar™ STEC</b>                    | ST160/ST162/ST163                   |
| <b>CHROMagar™ Y.enterocolitica</b>        | YE492                               |
| <b>CHROMagar™ MH Orientation</b>          | MH482/MH483                         |
| <b>CHROMagar™ C.difficile</b>             | CD122                               |
| <b>CHROMagar™ C3G<sup>R</sup></b>         | CG632/ CG633                        |
| <b>CHROMagar™ Vibrio</b>                  | VB910/VB912/VB913                   |
| <b>CHROMagar™ mSuperCARBA™</b>            | SC172/SC173                         |
| <b>CHROMagar™ Campylobacter</b>           | CP572/CP573                         |
| <b>CHROMagar™ Malassezia</b>              | MZ282/MZ283                         |
| <b>LIM RambaQUICK StrepB</b>              | LB008                               |

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