

## DECLARATION OF CONFORMITY EU



Fabricant Manufacturer Fabricante	Hersteller Fabricante Produttore	<b>CHROMagar™</b>
Règlement UE EU Regulation Reglamento UE	EU Verordnung Regulamento UE Regolamento UE	<b>Regulation (EU) 2017/746 of the European parliament and of the council of 5 April 2017 on <i>in vitro</i> diagnostic medical devices</b>
Normes Standards Norma	Normen Estandar Padrao	<b>EN ISO 13485 : 2016</b>

CHROMagar™ déclare par la présente que les produits CHROMagar™ de diagnostic *in vitro* (cf. annexe 1) sont conformes au Règlement (UE) 2017/746.

CHROMagar™ hereby declares that the CHROMagar™ *in vitro* diagnostic products (cf. annex 1) comply with Regulation (EU) 2017/746.

Por la presente, CHROMagar™ declara que sus productos de diagnóstico *in vitro* (cf. anexo 1) son conformes con el Reglamento (UE) 2017/746.

CHROMagar™ erklärt hiermit, dass die *In-vitro*-CHROMagar™-Produkte (cf. anlage 1) der Verordnung (EU) 2017/746 entsprechen.

La CHROMagar™ dichiara che i prodotti CHROMagar™ per la diagnostica *in vitro* (cf. annesso 1) sono conformi al Regolamento (UE) 2017/746.

Chromagar™ declara que os produtos de diagnóstico *in vitro* CHROMagar™ (cf. anexo 1) estão em conformidade com o Regulamento (UE) 2017/746.

Paris, 7<sup>th</sup> iune 2023

**ANNEX 1 – DECLARATION OF CONFORMITY EU - CHROMagar™ *in vitro* diagnosis products**

Medium	Product name	Reference	IVD Class	Basic UDI-DI	EMDN	GMDN
<b>CHROMagar™ Candida</b>	CHROMagar™ Candida	CA222	A	376034476CA2276	W0104030101	58585
		CA223-25				
		CA223-10kg				
<b>CHROMagar™ Candida Plus</b>	CHROMagar™ Candida Plus	CA242	A	376034476CA247A	W0104030101	58585
		CA243-25				
		CA243-10kg				
<b>CHROMagar™ StrepB</b>	CHROMagar™ StrepB base	SB282(B)	A	376034476SB28B89	W0104010101	58585
		SB283-25(B)				
		SB282(S1)				
<b>CHROMagar™ StrepB-S1</b>	CHROMagar™ StrepB-S1	SB283-25(S1)	A	376034476SB28S16P	W0104010104	58556
		SB282(S2)				
		SB283-25(S2)				
<b>CHROMagar™ LIM RambaQuick™ StrepB</b>	CHROMagar™ LIM RambaQuick™ StrepB base	LB082(B)	A	376034476LB08B5J	W0104010101	58684
		LB082(S)				
		SP372(B)				
<b>CHROMagar™ StrepA</b>	CHROMagar™ StrepA base	SP373-25(B)	A	376034476SP37BBD	W0104010101	58585
		SP373-10kg(B)				
		SP372(S1)				
<b>CHROMagar™ StrepA-S1</b>	CHROMagar™ StrepA-S1	SP373-25(S1)	A	376034476SP37S1BK	W0104010104	58556
		SP373-100(S1)				
		SP372(S2)				
<b>CHROMagar™ StrepA-S2</b>	CHROMagar™ StrepA-S2	SP373-25(S2)	A	376034476SP37S2BM	W0104010104	58556
		SP373-184(S2)				
		ST160(B)				
<b>CHROMagar™ STEC</b>	CHROMagar™ STEC base	ST162(B)	A	376034476ST16BBU	W0104010101	58585
		ST163-10kg(B)				
		ST160(S)				
<b>CHROMagar™ STEC supplement</b>	CHROMagar™ STEC supplement	ST162(S)	A	376034476ST16SCW	W0104010104	58556
		ST163-325(S)				
		VR952(B)				
<b>CHROMagar™ VRE</b>	CHROMagar™ VRE base	VR952(B)	A	376034476VR95BDL	W0104010101	58585
		VR953-10kg(B)				

	CHROMagar™ VRE supplement	VR952(S)	A	376034476VR95SEN	W0104010104	58556
		VR953-150(S)				
CHROMagar™ Serratia	CHROMagar™ Serratia base	SM302(B)	A	376034476SM30BA3	W0104010101	58585
	CHROMagar™ Serratia supplement	SM302(S)	A	376034476SM30SB5	W0104010104	58556
	CHROMagar™ mSuperCARBA™ base	SC172(B)	A	376034476SC17B88	W0104010101	58585
CHROMagar™ mSuperCARBA™	mSuperCARBA™ -S1	SC173-25(B)	A	376034476SC17S16N	W0104010104	58556
		SC173-10kg(B)				
		SC172(S1)				
		SC173-25(S1)				
CHROMagar™ mSuperCARBA™	-S2	SC173-105(S1)	A	376034476SC17S26Q	W0104010104	58556
		SC172(S2)				
		SC173-25(S2)				
CHROMagar™ COL-APSE	CHROMagar™ COL-APSE base	CO262(B)	A	376034476CO26B5E	W0104010101	58585
	CHROMagar™ COL-APSE suppl.	CO262(S)	A	376034476CO26S6G	W0104010104	58556
CHROMagar™ LIN-R	CHROMagar™ LIN-R base	LN762(B)	A	376034476LN76B93	W0104010101	58585
	CHROMagar™ LIN-R suppl.	LN762(S)	A	376034476LN76SA5	W0104010104	58556
CHROMagar™ C.difficile	CHROMagar™ C.difficile base	CD122(B)	A	376034476CD12B2G	W0104010101	58585
	CHROMagar™ C.difficile supplement	CD122(S)	A	376034476CD12S3J	W0104010104	58556
CHROMagar™ Y.enterocolitica	CHROMagar™ Y.enterocolitica base	YE492(B)	A	376034476YE49BBB	W0104010101	58585
	CHROMagar™ Y.enterocolitica suppl.	YE492(S)	A	376034476YE49SCF	W0104010104	58556
CHROMagar™ Staph aureus	CHROMagar™ Staph aureus	TA672	A	376034476TA67BK	W0104010101	58585
	CHROMagar™ MRSA	MR502	A	376034476MR50C6	W0104010101	58585
CHROMagar™ MRSA	CHROMagar™ MRSA supplement	SU620	A	376034476SU620BE	W0104010104	58556
	CHROMagar™ MRSA Base A	MR533-10kg(A)	A	376034476MR53A9M	W0104010101	58585
	CHROMagar™ MRSA Liquid B	MR513-125(B)	A	376034476MR51B9H	W0104010104	58556
	CHROMagar™ MRSA Mix C	MR513-125(C)	A	376034476MR51C9K	W0104010104	58556
	CHROMagar™ MRSA supplement	SU625-BA	A	376034476SU625BQ	W0104010104	58556
CHROMagar™ Acinetobacter	CHROMagar™ Acinetobacter base	AC092(B)	A	376034476AC09B23	W0104010101	58585
	CHROMagar™ Acinetobacter supplement	AC092(S)	A	376034476AC09S35	W0104010104	58556
	CHROMagar™ MDR Selective suppl.	CR102	A	376034476CR109L	W0104010104	58556
CHROMagar™ Campylobacter	CHROMagar™ Campylobacter base	CP572(B)	A	376034476CP57B67	W0104010101	58585
	CHROMagar™ Campylobacter suppl.	CP573-25(B)	A	376034476CP57S79	W0104010104	58556
CHROMagar™ Salmonella	CHROMagar™ Salmonella	CP572(S)	A	376034476CP57S79	W0104010104	58556
		CP573-25(S)				
		SA132	A	376034476SA13AM	W0104010101	58585
		SA133-25				

<b>CHROMagar™ Orientation</b>	CHROMagar™ Orientation	RT412	A	3760344476RT41DJ	W0104010101	58585
		RT413-25				
		RT413-10kg				
		RT-413-25kg				
<b>CHROMagar™ ESBL supplement</b>	CHROMagar™ ESBL supplement	ES372	A	3760344476ES37AT	W0104010104	58556
		ES373-25				
<b>CHROMagar™ KPC supplement</b>	CHROMagar™ KPC supplement	KP102	A	3760344476KP10B2	W0104010104	58556
		KP103-25				
<b>CHROMagar™ C3GR supplement</b>	CHROMagar™ C3GR supplement	CG632	A	3760344476CG638J	W0104010104	58556
		CG633-25				
<b>CHROMagar™ B.cepacia</b>	CHROMagar™ B.cepacia	BK992	A	3760344476BK999L	W0104030101	58585

## ATITIKTIES DEKLARACIJA EU



Fabricant Gamintojas Gamintojas	Pardavėjas Gamintojas Produttore	<b>CHROMagar™</b>
ES teisės aktai ES reglamentas Reglamento EU	ES Verordnung Reglamento UE Regolamento UE	<b>2017 m. balandžio 5 d. Europos Parlamento ir Tarybos reglamentas (ES) 2017/746 dėl <i>in vitro</i> diagnostikos medicinos prietaisų</b>
Normos Standartai Norma	Normen Estandar Padrao	<b>EN ISO 13485 : 2016</b>

CHROMagar™ déclare par la présente que les produits CHROMagar™ de diagnostic *in vitro* (plg. 1 prieda) sont conformes au Règlement (UE) 2017/746.

CHROMagar™ pareiškia, kad CHROMagar™ *in vitro* diagnostikos produktai (žr. 1 prieda) atitinka Reglamento (ES) 2017/746 reikalavimus.

Por la presente, CHROMagar™ declara que sus productos de diagnóstico *in vitro* (cf. anexo 1) son conformes con el Reglamento (UE) 2017/746.

CHROMagar™ erklärt hiermit, dass die In-vitro-CHROMagar™-Produkte (plg. anlage 1) der Verordnung (EU) 2017/746 entsprechen.

La CHROMagar™ dichiara che i prodotti CHROMagar™ per la diagnostica *in vitro* (cf. annesso 1) sono conformi al Regolamento (UE) 2017/746.

Chromagar™ declara que os produtos de diagnóstico *in vitro* CHROMagar™ (cf. anexo 1) estão em conformidade com o Regulamento (UE) 2017/746.

Paryžius, 2023 m.

  
Kokybės vadybininkė

**1 PRIEDAS - ES - CHROMagar™ in vitro diagnostikos produktai - atitikties deklaracija**

Vidutinis	Produkto pavadinimas	Nuoroda	IVD Klasė	Pagrindinis UDI-DI	EMDN	GMDN
CHROMagar™ Candida	CHROMagar™ Candida	CA222	A	376034476CA2276	W0104030101	58585
		CA223-25				
		CA223-10 kg				
CHROMagar™ Candida Plus	CHROMagar™ Candida Plus	CA242	A	376034476CA247A	W0104030101	58585
		CA243-25				
		CA243-10 kg				
CHROMagar™ StrepB	CHROMagar™ StrepB bazė	SB282(B)	A	376034476SB28B89	W0104010101	58585
		SB283-25(B)				
		SB282(S1)				
		SB283-25(S1)				
		SB282(S2)				
		SB283-25(S2)				
CHROMagar™ LIM RambaQuick™ StrepB	CHROMagar™ LIM RambaQuick™ StrepB bazė	LB082(B)	A	376034476LB08B5J	W0104010101	58684
	CHROMagar™ LIM RambaQuick™ StrepB priedas	LB082(S)	A	376034476LB08S6L	W0104010104	58556
CHROMagar™ StrepA	CHROMagar™ StrepA bazė	SP372(B)	A	376034476SP37BBD	W0104010101	58585
		SP373-25(B)				
		SP373-10 kg(B)				
		SP372(S1)				
		SP373-25(S1)				
		SP373-100(S1)				
CHROMagar™ StrepA	CHROMagar™ StrepA-S1	SP372(S2)	A	376034476SP37S1BK	W0104010104	58556
		SP373-25(S2)				
		SP373-184(S2)				
CHROMagar™ STEC	CHROMagar™ STEC bazė	ST160(B)	A	376034476ST16BBU	W0104010101	58585
		ST162(B)				
		ST163-10 kg(B)				
		ST160(S)				
		ST162(S)				
		ST163-325(S)				
CHROMagar™ VRE	CHROMagar™ VRE bazė	VR952(B)	A	376034476VR95BDL	W0104010101	58585
		VR953-10 kg(B)				

CHROMagar™ Serratia	CHROMagar™ VRE priedas	VR952(S) VR953-150(S)	A	376034476VR95SEN	W0104010104	58556
	CHROMagar™ Serratia bazē	SM302(B)	A	376034476SM30BA3	W0104010101	58585
	CHROMagar™ Serratia priedas	SM302(S) SC172(B)	A	376034476SM30SB5	W0104010104	58556
CHROMagar™ mSuperCARBA™ bazē	CHROMagar™ mSuperCARBA™ bazē	SC173-25(B) SC173-10 kg(B)	A	376034476SC17B88	W0104010101	58585
	CHROMagar™ mSuperCARBA™-S1	SC172(S1) SC173-25(S1) SC173-105(S1)	A	376034476SC17S16N	W0104010104	58556
	CHROMagar™ mSuperCARBA™-S2	SC172(S2) SC173-25(S2) SC173-235(S2)	A	376034476SC17S26Q	W0104010104	58556
CHROMagar™ COL-APSE	CHROMagar™ COL-APSE bazē	CO262(B)	A	376034476CO26B5E	W0104010101	58585
	CHROMagar™ COL-APSE suppl.	CO262(S)	A	376034476CO26S6G	W0104010104	58556
CHROMagar™ LIN-R	CHROMagar™ LIN-R bazē	LN762(B)	A	376034476LN76B93	W0104010101	58585
	CHROMagar™ LIN-R suppl.	LN762(S)	A	376034476LN76SA5	W0104010104	58556
CHROMagar™ C.difficile	CHROMagar™ C.difficile bazē	CD122(B)	A	376034476CD12B2G	W0104010101	58585
	CHROMagar™ C.difficile priedas	CD122(S)	A	376034476CD12S3J	W0104010104	58556
CHROMagar™ Y.enterocolitica	CHROMagar™ Y.enterocolitica bazē	YE492(B)	A	376034476YE49BBD	W0104010101	58585
	CHROMagar™ Y.enterocolitica suppl.	YE492(S)	A	376034476YE49SCF	W0104010104	58556
CHROMagar™ Staph aureus	CHROMagar™ Staph aureus	TA672	A	376034476TA67BK	W0104010101	58585
	CHROMagar™ MRSA	MR502	A	376034476MR50C6	W0104010101	58585
CHROMagar™ MRSA	CHROMagar™ MRSA priedas	SU620	A	376034476SU620BE	W0104010104	58556
	CHROMagar™ MRSA Base A	MR533-10kg(A)	A	376034476MR53A9M	W0104010101	58585
	CHROMagar™ MRSA Liquid B	MR513-125(B)	A	376034476MR51B9H	W0104010104	58556
	CHROMagar™ MRSA mišinys C	MR513-125(C)	A	376034476MR51C9K	W0104010104	58556
	CHROMagar™ MRSA priedas	SU625-BA	A	376034476SU625BQ	W0104010104	58556
CHROMagar™ Acinetobacter	CHROMagar™ Acinetobacter bazē	AC092(B)	A	376034476AC09B23	W0104010101	58585
	CHROMagar™ Acinetobacter priedas	AC092(S)	A	376034476AC09S35	W0104010104	58556
	CHROMagar™ MDR Selective suppl.	CR102	A	376034476CR109L	W0104010104	58556
CHROMagar™ Campylobacter	CHROMagar™ Campylobacter bazē	CP572(B) CP573-25(B)	A	376034476CP57B67	W0104010101	58585
	CHROMagar™ Campylobacter suppl.	CP572(S) CP573-25(S)	A	376034476CP57S79	W0104010104	58556
CHROMagar™ Salmonella	CHROMagar™ Salmonella	SA132 SA133-25	A	376034476SA13AM	W0104010101	58585

<b>CHROMagar™ orientacija</b>	CHROMagar™ orientacija	RT412	A	376034476RT41DJ	W0104010101	58585
		RT413-25				
		RT413-10 kg				
		RT-413-25 kg				
<b>CHROMagar™ ESBL priedas</b>	CHROMagar™ ESBL priedas	ES372	A	376034476ES37AT	W0104010104	58556
		ES373-25				
<b>CHROMagar™ KPC priedas</b>	CHROMagar™ KPC priedas	KP102	A	376034476KP10B2	W0104010104	58556
		KP103-25				
<b>CHROMagar™ C3GR priedas</b>	CHROMagar™ C3GR priedas	CG632	A	376034476CG638J	W0104010104	58556
		CG633-25				
<b>CHROMagar™ B.cepacia</b>	CHROMagar™ B.cepacia	BK992	A	376034476BK999L	W0104030101	58585

