



# DICHIARAZIONE DI CONFORMITA' / DECLARATION OF CONFORMITY DECLARATION DE CONFORMITÈ/ KONFORMITÄTSEKTLÄRUNG

**Nome e indirizzo della ditta**  
*Name and address of the firm*  
*Name und Adresse der Firma*  
*Nom et adresse de l'entreprise*

**BIOSIGMA S.r.l.**  
Via Valletta, 6 – Zona Ind. Cantarana  
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<http://www.biosigma.com>

**Dichiariamo sotto nostra responsabilità che il dispositivo medico-diagnostico in vitro:**  
*We declare under our sole responsibility that the in vitro diagnostic medical device:*  
*Wir erklären in alleiniger Verantwortung, dass das Medizinprodukt für die In-vitro-Diagnostik:*  
*Nous déclarons sous notre propre responsabilité que le dispositif médical de diagnostique in vitro:*

**Famiglia: VETRINI PER MICROSCOPIA**  
**MICROSCOPE SLIDES / MICROSCOPIE LAMES**  
**OBJEKTTRÄGER**  
Vedi elenco allegato / *See the enclosed list*  
*Produkt der Liste beiliegend / Voir liste ci-joint /*

<b>Codice CND</b>	W05039002	Vetrini per analisi di campioni
<b>EDMA code:</b> (Version 2007)	2901	Other Instruments
<b>GMDN code:</b>	0	No Equivalent GMDN Term

**Classificazione secondo la direttiva relativa ai dispositivi medico-diagnostici in vitro 98/79/CE.**  
*Classification according to the directive on in vitro diagnostic medical devices 98/79/EC.*  
*Klassifizierung nach der Richtlinie über In-vitro-Diagnostika 98/79/EC.*  
*Classification selon la directive relative aux dispositifs médicaux de diagnostic in vitro 98/79/CE.*

- Dispositivo dell'elenco A, allegato II / *Produkt der Liste A, Anhang II / Dispositif de la liste B, annexe II / Device of List A, Annex II*
- Dispositivo dell'elenco B, allegato II / *Device of List B, Annex II / Produkt der Liste B, Anhang II / Dispositif de la liste B, annexe II*
- Dispositivo per testautodiagnostico non elencato nell'allegato II / *Device for self-testing not listed in Annex II Produkt zur Eigenanwendung, das nicht in Anhang II genannt ist / Dispositif destiné à l'autodiagnostic non listé dans l'annexe II*
- Altro dispositivo / Other device Sonstiges Produkt / Autre dispositif**

**soddisfa tutte le disposizioni della direttiva relativa ai dispositivi medico-diagnostici in vitro 98/79/CE che lo riguardano.**  
*meets all the provisions of the directive on in vitro diagnostic medical devices 98/79/EC which apply to it.*  
*allen Anforderungen der Richtlinie über In-vitro-Diagnostika 98/79/EC entspricht, die anwendbar sind.*  
*remplit toutes les exigences de la directive relative aux dispositifs médicaux de diagnostic in vitro 98/79/CE qui le concernent.*

**Procedimento di valutazione della conformità:**  
*Conformity assessment procedure:*  
*Konformitätsbewertungsverfahren:*  
*Procédure d'évaluation de la conformité:*

**Allegato III (escluso punto 6)**  
Annex III (excluding point 6)  
*Anhang III (mit Ausnahme von Punkt 6)*  
*Annexe III (à l'exclusion, point 6)*

**Organo incaricato della valutazione della conformità (se consultato):**  
*Notified Body (if consulted):*  
*Konformitätsbewertungsstelle (falls beigezogen):*  
*Organe resp. de l'évaluat. de la conform.(si consult):*

N.A.



CONA 06/06/2017  
**Luogo, data / Place, date / Ort, Datum / Lieu, date**

MARCOLIN MARTINO – Consigliere Delegato  
**Nome e funzione / Name and function / Name und Funktion / Nom et fonction**



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P.IVA IT 03328440270 | N. 298577 R.E.A. di Venezia | Registro A.E.E. IT0903000005843 | R.N.P.P.A. IT11080P00002626



# DICHIARAZIONE DI CONFORMITA' / DECLARATION OF CONFORMITY DECLARATION DE CONFORMITÉ/ KONFORMITÄTSEKTLÄRUNG

Le DICHIARAZIONI DI CONFORMITA' alla Direttiva 98/79/CE relative alle varie famiglie di prodotti si riferiscono ai seguenti codici in dettaglio:

The DECLARATIONS OF CONFORMITY to Directive 98/79/EC concerning the various families of products make reference to following code numbers:

VETRINI PER MICROSCOPIA		MICROSCOPE SLIDES
REF	PORTAOGGETTO Dim. ~ 26 x 76 mm	SLIDES Dim. ~ 26 x 76 mm
<b>NORMALI</b>		
VBS653/A	TAGLIATI	CUT EDGES
VBS654/A	TAGLIATI con DOPPIA AREA SMERIGLIATA	CUT EDGES WITH DOUBLE FROSTED AREA
VBS655/A	MOLATI	GROUND EDGES
<b>SILVER QUALITY</b>		
VBS653	TAGLIATI – SILVER QUALITY	CUT EDGES - SILVER QUALITY
VBS653/50	TAGLIATI – SILVER QUALITY - conf. 50 pz.	CUT EDGES - SILVER QUALITY – conf. 50 pcs.
VBS654	TAGLIATI con DOPPIA AREA SMERIGLIATA – SILVER QUALITY	CUT EDGES WITH DOUBLE FROSTED AREA - SILVER QUALITY
VBS654/50	TAGLIATI con DOPPIA AREA SMERIGLIATA – SILVER QUALITY- conf. 50 pz.	CUT EDGES WITH DOUBLE FROSTED AREA - SILVER QUALITY– conf. 50 pcs.
VBS655	MOLATI – SILVER QUALITY	GROUND EDGES - SILVER QUALITY
VBS655/50	MOLATI – SILVER QUALITY- conf. 50 pz.	GROUND EDGES - SILVER QUALITY– conf. 50 pcs.
VBS656	MOLATI con DOPPIA AREA SMERIGLIATA - SILVER QUALITY	GROUND EDGES WITH DOUBLE FROSTED AREA - SILVER QUALITY
VBS656/50	MOLATI con DOPPIA AREA SMERIGLIATA - SILVER QUALITY- conf. 50 pz.	GROUND EDGES WITH DOUBLE FROSTED AREA - SILVER QUALITY– conf. 50 pcs.
VBS656/AR	MOLATI con AREA COLORATA ARANCIONE - SILVER QUALITY	GROUND EDGES WITH ORANGE COULORED AREA - SILVER QUALITY
VBS656/AR50	MOLATI con AREA COLORATA ARANCIONE - SILVER QUALITY- conf. 50 pz.	GROUND EDGES WITH ORANGE COULORED AREA - SILVER QUALITY– conf. 50 pcs.
VBS656/AZ	MOLATI con AREA COLORATA AZZURRA - SILVER QUALITY	GROUND EDGES WITH LIGHT BLUE COULORED AREA - SILVER QUALITY
VBS656/AZ50	MOLATI con AREA COLORATA AZZURRA - SILVER QUALITY- conf. 50 pz.	GROUND EDGES WITH LIGHT BLUE COULORED AREA - SILVER QUALITY– conf. 50 pcs.
VBS656/B	MOLATI con AREA COLORATA BIANCA - SILVER QUALITY	GROUND EDGES WITH WHITE COULORED AREA - SILVER QUALITY
VBS656/B50	MOLATI con AREA COLORATA BIANCA - SILVER QUALITY- conf. 50 pz.	GROUND EDGES WITH WHITE COULORED AREA - SILVER QUALITY– conf. 50 pcs.
VBS656/G	MOLATI con AREA COLORATA GIALLA - SILVER QUALITY	GROUND EDGES WITH YELLOW COULORED AREA - SILVER QUALITY
VBS656/G50	MOLATI con AREA COLORATA GIALLA - SILVER QUALITY- conf. 50 pz.	GROUND EDGES WITH YELLOW COULORED AREA - SILVER QUALITY– conf. 50 pcs.
VBS656/RA	MOLATI con AREA COLORATA ROSA – SILVER QUALITY	GROUND EDGES WITH PINK COULORED AREA - SILVER QUALITY
VBS656/RA50	MOLATI con AREA COLORATA ROSA – SILVER QUALITY- conf. 50 pz.	GROUND EDGES WITH PINK COULORED AREA - SILVER QUALITY– conf. 50 pcs.
VBS656/V	MOLATI con AREA COLORATA VERDE - SILVER QUALITY	GROUND EDGES WITH GREEN COULORED AREA - SILVER QUALITY
VBS656/V50	MOLATI con AREA COLORATA VERDE - SILVER QUALITY- conf. 50 pz.	GROUND EDGES WITH GREEN COULORED AREA - SILVER QUALITY– conf. 50 pcs.
<b>REF</b>		<b>COVER SLIPS</b>
VBS633	18 x 18 mm	18 x18 mm
VBS634	20 x 20 mm	20 x 20 mm
VBS636	22 x 22 mm	22 x 22 mm
VBS637	24 x 24 mm	24 x 24 mm
VBS638	24 x 32 mm	24 x 32 mm



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## DICHIARAZIONE DI CONFORMITA' / DECLARATION OF CONFORMITY DECLARATION DE CONFORMITÈ/ KONFORMITÄTSERKLÄRUNG

VBS649	24 x 40 mm	24 x 40 mm
VBS650	24 x 50 mm	24 x 50 mm
VBS651	24 x 60 mm	24 x 60 mm

**Il presente Elenco si riferisce ai dispositivi medico-diagnostici in vitro registrati da Biosigma S.r.l. presso il Ministero della Sanità alla data riportata nella Dichiarazione di Conformità.**

*This List refers to in vitro diagnostic medical devices registered by Biosigma S.r.l. to Ministry for Health at the date reported on the Declaration of Conformity.*



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