



DICHIARAZIONE DI CONFORMITA' / DECLARATION OF CONFORMITY DECLARATION DE CONFORMITÉ/ KONFORMITÄTSERKLÄRUNG

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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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 /

| | | |
|-------------------------------------|-----------|---------------------------------|
| Codice CND | W05039002 | Vetrini per analisi di campioni |
| EDMA code: (Version 2007) | 2901 | Other Instruments |
| GMDN code: | 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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Email info@biosigmaeu.com | www.biosigma.it www.biosigma.com | Cap. Soc. 99.000 € i.v. | C.F. 02173800281 |
P.IVA IT 03328440270 | N. 298577 R.E.A. di Venezia | Registro A.E.E. IT0903000005843 | R.N.P.P.A. IT11080P00002626



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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 |
| NORMALI | | |
| VBS653/A | TAGLIATI | CUT EDGES |
| VBS654/A | TAGLIATI con DOPPIA AREA SMERIGLIATA | CUT EDGES WITH DOUBLE FROSTED AREA |
| VBS655/A | MOLATI | GROUND EDGES |
| SILVER QUALITY | | |
| 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. |
| REF | | COVER SLIPS |
| 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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| | | |
|--------|------------|------------|
| 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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