



**Biosigma s.r.l.**

**a Dominique Dutscher Company**

Via Valletta, 6 | 30010 Cantarana di Cona (VE), Italy | Tel. ++39 0426 302224 (r.a.) |

Fax ++39 0426 302228 | SMS ++39 348 4077376 |

E-mail info@biosigmaeu.com | http://www.biosigma.com |

**M521D**

Last Updating  
26<sup>th</sup> March 2013

## TECHNICAL DATA SHEET

### Tissue embedding and Biopsy cassettes



patent pending

Dimensions : 28 x 40 x 7 mm



Embedding cassettes with removable cover. Made of acetalic resin, resistant to solvents decalcificants histological solutions and ultrasound techniques. Writing space for sample identifications. Suitable also to automatic printers.



### Innovative closing system

Object of the inventions is to eliminate the inconvenience of cassette's accidental opening during processing resulting in a loss of the sample and at the same time to allow an easy opening of cassette.



Photo 1

Photo 1: This object is achieved with the presence of a hook closure front facing the inside of the cassette that in case of voluminous samples resists to accidental opening.



Photo 2

Photo 3: Moreover, the presence of special ribs located on the lid, prevents the forward movement thereof with respect to the body of the cassette, ensuring the insertion and sealing of the two rear hooks into the appropriate slits (Photo 2), thus avoiding the opening of the cassette on the back.



Photo 3



Photo 4

45°

Photo 4: The opening tab does not present sharp edges and is structured so as to allow easy opening by the operator. Anterior writing area is at 45° angle. Made of acetal polymer.

### IN VITRO DIAGNOSTIC MEDICAL DEVICE CE FOR PROFESSIONAL USE ONLY

#### RECOMMENDATIONS FOR USE (as for information)

- Use only for laboratory analysis,
- Do not use after expiry or if box is already open,
- Do not vary the intended purpose of the product,
- Keep out of reach of children,
- Store in dry place and far from the direct light,
- Waste disposal: utilize the provided D.P.I and discharge under the laws in force.



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### Histology cassettes

Cassettes in Pom detachable cover, 40 x 7 x 28 mm with rectangular holes 5 x 1 mm

Histology		
Ref.	Color	
BSI102	white	
BSI1022	yellow	
BSI1024	pink	
BSI1026	green	
BSI1027	orange	
BSI1028	light blue	

### Biopsy cassettes

Cassettes in Pom detachable cover, 40 x 7 x 28 mm with square holes 1 x 1 mm

Biopsy		
Ref.	Color	
BSI103	white	
BSI1032	yellow	
BSI1034	pink	
BSI1036	green	
BSI1037	orange	
BSI1038	light blue	

### Manufacturer definition

The manufacturer of the products HISTOLOGY AND BIOPSY CASSETTES is:

**BIOSIGMA S.r.l. - Via Valletta, 6 - 30010 - Cantarana di Cona (VE) - ITALY**

**Tel. +39.0426.302224 - Fax +39.0426.302228**

**E-mail: [info@biosigma.copm](mailto:info@biosigma.copm) - <http://www.biosigma.com>**

### Destination use

The products of the family HISTOLOGY/BIOPSY CASSETTES are disposable products designed to contain tissues samples and organs of biological origin for a diagnostic in vitro examination.

### For in vitro use only

The use and the manipulation of the devices **are reserved to the medical and technical staff** with the necessary professional qualification.

### Classification

In order to the Directive 98/79/CE concerning medical-diagnostic in vitro devices receipt in Italy with D.L. n. 332 G.U.R.I. n. 269 dated 17 November 2000, Biosigma s.r.l., defines all the components of the above-state family as medical-diagnostic in vitro devices and it classifies as "Other medical-diagnostic in vitro devices", in order to make conformable the attachment III of the directive.

### Materials

The materials used for production of in vitro diagnostic medical device have been selected on the base of the properties indicated for individual destination use.

The devices HISTOLOGY and BIOPSY CASSETTES are produced in POLYOXYMETHYLENE (POM). The **POLYOXYMETHYLENE** is a product obtained from the polymerization of the formaldehyde, light, in frangible, optimal chemical resistance to bases and dissolvents used in pathological anatomy.

### Materials used for packaging of products

All components used for packaging aren't polluting products suitable to the scope to which they are destined.

The Declaration of Conformity in accordance to the **Directive 98/79/CE** is available, on request, to the Quality Department Biosigma S.r.l.



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## TECHNICAL DATA SHEET

### Interpretation of the symbols on the package

	This product fulfils the requirements of Directive 98/79/EC on in vitro diagnostic medical devices		Symbol for "Keep dry"
	Symbol for "Do not reuse"		Symbol for "batch code"
	Symbol for "Consult Instructions for Use"		Symbol for "Use by"
	Symbol for "temperature limitation"		Symbol for "Manufacturer"
	Symbol for "In Vitro Diagnostic Medical Device"		Symbol for "Fragile, handle with care"
	Symbol for "Method of sterilization using irradiation"		Symbol for "Method of sterilization using ethylene oxide"
	Symbol for "Do not use if package damaged"		Symbol for "Keep away from heat"