



Biosigma s.r.l.

a Dominique Dutscher Company

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M521D

Last Updating
07th September 2011

TECHNICAL DATA SHEET

REDUCTION CUPS

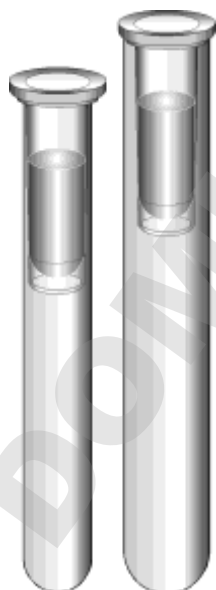
2 types of REDUCTIONS for automatism with level detector



Family: SAMPLE CUPS		Vol. ml	Dim. mm
BSA636	Reduction cups for tubes Ø 13 mm in PS <i>Normal Type, for tubes of 5 ml</i>	1	Ø 13 x 30
BSA646	Reduction cups for tubes Ø 16 mm in PS <i>Big Type, for tubes of 10 ml</i>	2	Ø 16 x 30

IN VITRO DIAGNOSTIC MEDICAL DEVICE CE FOR PROFESSIONAL USE ONLY

- Use only for laboratory analysis
- Use gloves: contamination risk if contents leaks
- Keep out of flame or heat sources which might damage the product
- Do not use after expiry date
 - Do not vary the intended purpose of the product
 - Keep out of reach of children
 - Store in dry place, temperature range: min. - 10°C max 50°C
 - Disposal: use appropriate personal protective equipment and act according to applicable regulations



MANUFACTURER DEFINITION

BIOSIGMA s.r.l.

Via Valletta, 6 - 30010 - Cantarana di Cona (VE) - ITALY

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DESTINATION USE

Reduction Cups are disposable labware intended to be used on laboratory to contain biological liquids for in vitro diagnostic analysis.

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.



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USE:

- Take a part of the sample
- Transfer it in the Reducer
- Put the Reducer in the first tube
- Start the analysis

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 17th 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 utilized for the production of the in vitro labware devices are selected on the base of the properties indicated for the individual destination use.

The devices **Reduction Cups** are manufactured in POLYSTYRENE (PS) ;















The polystyrene is rigid and non-toxic, with excellent dimensional stability and good chemical resistance to aqueous solution but limited resistance to solvents. This clear material is commonly used for disposable laboratory products. Products made of polystyrene are brittle at ambient temperature and many crack of break if dropped from benchtop height.

MATERIALS USED FOR THE PACKAGING OF THE PRODUCTS

All the materials used for the packaging are products made in materials not polluting, suitable to the aim.

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

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"