



TECHNICAL DATA SHEET

REF: BSA021 CE

**Cones OLLY Type, Vol. 1.5 ml, Ø 10 x 40 mm,
graduated, neutral in PP.
Box 10 X 1000 Pcs.**



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
- Autoclavable at 121°C for 20 minutes
- Disposal: use appropriate personal protective equipment and act according to applicable regulations

MANUFACTURER DEFINITION

BIOSIGMA s.r.l.
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DESTINATION USE

CONES OLLY TYPE are devices of the family "TEST-TUBES & STOPPERS", 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.





Biosigma s.r.l.

a Dominique Dutscher Company

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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 classifies it 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 CONES OLLY TYPE are product in Polypropylene (PP).

The **polypropylene** is a translucent, light, resistant to autoclaving and sterilization. It has excellent characteristics of chemical resistance (to ambient temperature it does not come melted from some dissolvent).

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"