



**Description:** Cupule chirurgicale

<b>Composition:</b>	PP pharmaceutical grade.
<b>Latex:</b>	Free
<b>PVC:</b>	Free
<b>Re use:</b>	No
<b>CMR:</b>	Free
<b>Endocrine Disruptors:</b>	Free
<b>Colour:</b>	translucent
<b>Capacity:</b>	120 mL
<b>Diameter:</b>	84,0 mm
<b>Sterilization method:</b>	Ethylene Oxide
<b>Shelf life:</b>	60 months
<b>CFU/g</b>	N.A.
<b>Sterility Assur. Level_SAL</b>	≤10 <sup>-6</sup>
<b>Height</b>	35 mm

STERILE EO



isento  
Latex  
free

isento  
PVC  
free





<b>Nr and Revision Date:</b>	31 -- 2022/05/05
<b>CE Class:</b>	Ila
<b>CE mark:</b>	CE1639
<b>Compliance with:</b>	MDD 93/42/EEC amended by 2007/47/EC

BS\_5452\_1997-Specification for hospital hollow-ware made of plastics material (Partial compliance:non-compliance of 3. Dimensions, 5. Design and 10. Effect of sterilization as these are single-use devices it was not considered 50 cycles of sterilization acc. Appendix A) and 12. Marking absence of information on b) number of this British Standard and c) information regarding type and size engraved on the under surface). ; EN\_ISO\_13485.2016 ; EN\_ISO\_13485.2016\_AC18 ; EN\_ISO\_134852016\_A11 ; EN 556-1.2001\_AC.2006-(Not applicable) ; ISO\_11135.2014 ; EN\_ISO\_11135.2014\_A1.2019-(Not applicable) ; EN\_ISO\_11607\_1\_2020 ; EN\_ISO\_11607-2.2020 ; CEN\_ISO\_TS\_16775\_2021 ; ISO\_TS\_16775.2014 ; ASTM\_F1980\_16 ; ISO\_14644-1.2015 ; ISO\_14644-5\_2004 ; ISO\_14698\_1\_2003 ; EN\_ISO\_14971.2012 ; EN\_ISO\_15223-1.2016 ; EN\_ISO\_10993-1-2020 ; EN\_1041.2008\_A1.2013 ; EN\_ISO\_10993-18\_2020 ; EN\_ISO\_14971\_2019 ; EN\_ISO\_14971\_2019\_A11 ; EN\_ISO10993-1.09\_AC.10 ; EN\_ISO\_10993-18.2009 ; EN\_ISO\_15223-1.2021 ; EN\_ISO\_20417\_2021 ; ISTA Standard 2A ; ASTM D4169 ; ASTM D4332\_01 ; ICH Q1A (2003) ; ISO\_2759.2014 ; ISO\_3037\_2013 ;

<b>Applicable norms:</b>	
<b>GMDN:</b>	42891 - General-purpose bowl, single-use

**Important Notes:** Plastic bag inside carton box

Level	Type	Dimension	Stamp	Labels
 1	1 Flexible peel-open pack	134x140mm		
 2	240 Carton box	786x386x321mm		labeled

<b>Basic UDI</b>	56056221200002HC
	EAN 1th level/nivel:05605622050997
	EAN 2th level/nivel:15605622050994

**Important Notes:** The device is intended to be used on a single patient during one single procedure to prevent risks from contamination, including possible infections, and/or functional damage.

**Storage instructions** Store in a dry place at room temperature and protect from sunlight. The product has a good stability and therefore, normal conditions of medical devices storage shall apply.

**Waste instructions** No special requirements. The waste must be disposed according to local legal regulations for the disposable of medical waste.

**Intended use**

- To temporarily hold organs or tissues.-
- To hold, or for preparation and dilution of medicines, solutions or IV fluids to prepare medical devices such as catheters.-
- To hold aqueous, saline solutions for irrigation.-
- To hold antiseptics for disinfection of skin or mucosa, or for wound cleansing.-

To hold and/or transfer instruments and/or other medical devices such as swabs, sharps or trocars. Also to hold solutions for instrument cleansing during surgical procedures. -

To prepare substances (such as, bone cement) for application to the patient.-

Healthcare professionals should select a device with a suitable capacity and with an ergonomic design, appropriate for the specific intended purpose.-

*Any modification of the product as presented or any use out of its intended use are not of the manufacturer responsibility.*

**Environment - Packaging waste**

Weight (gr) of packing material used in 100 pcs

642

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