

**Description:** Surgical bowl

<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>Weight/pc</b>	Approx. 7,5 g
<b>Tested in accordance w/</b>	BS5452:1977(adapted)
<b>Height</b>	35 mm
<b>Graduation:</b>	Scale in mL and FLOZ

STERILE EO



isento  
Latex  
free

isento  
PVC  
free



<b>Nr and Revision Date:</b>	43 -- 2023/08/23
<b>CE Class:</b>	Ila
<b>CE mark:</b>	CE1639
<b>Compliance with:</b>	MDD 93/42/EEC amended by 2007/47/EC

<b>Applicable norms:</b>	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 AC:2018 ; EN ISO 13485:2016 A11:2021 ; EN 556-1:2001 AC:2006-(Not applicable) ; EN ISO 11135:2014 ; EN ISO 11135:14 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 15223-1:2016 ; EN ISO 10993-1:2020 ; EN ISO 10993-18:2020 ; EN ISO 14971:2019 ; EN ISO 14971:2019 A11:2021 ; EN ISO 15223-1:2021 ; EN ISO 20417:2021 ; ISTA Standard 2A ; ASTM D4169-22 ; ICH Q1A (2003) ; ISO 2759:2014 ; ISO 3037:2013 ;
<b>GMDN:</b>	42891 - General-purpose bowl, single-use

**Important Notes:** Plastic sleeve inside carton boxes

Level	Type	Dimension	Stamp	Labels
1	1 Flexible peel-open pack	134x140mm		
2	240 Plastic bag			labeled
3	240 Carton box	786x386x321mm		labeled

<b>Basic UDI</b>	56056221200002HC
	EAN 1th level/nivel:05605622229393
	EAN 2th level/nivel:05605622429397
	EAN Carton Box/Caixa:05605622029399

<b>Important Notes:</b>	-Not intended to be used for preparation of bone cement.
<b>Important Notes:</b>	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	Dispose according to local laws rules, regulations and/or infection prevention standards for urban waste, to minimize potential risk of contamination, infection or pollution.
Intended purpose	<p>To temporarily hold organs or tissues.</p> <p>To hold, or for preparation and dilution of medicines, solutions or IV fluids to prepare medical devices such as catheters.</p> <p>To hold aqueous, saline solutions for irrigation.</p> <p>To hold antiseptics for disinfection of skin or mucosa, or for wound cleansing.</p> <p>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.</p> <p>Healthcare professionals should select a device with a suitable capacity and with an ergonomic design, appropriate for the specific intended purpose.</p> <p><i>Any modification of the product as presented or any use out of its intended purpose are not of the manufacturer responsibility</i></p>

Non-harmonized symbols used in article labeling		F/invasive procedures,prior to use please flush the container w/sterile solution
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Environment - Packaging waste	Weight (gr) of packing material used in 100 pcs	642
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ISSUED BY: Quality Management Department, 2023/09/01

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