

Description: Surgical bowl

Composition:	PP pharmaceutical grade.
Latex:	Free
PVC:	Free
Re use:	No
CMR:	Free
Endocrine Disruptors:	Free
Colour:	translucent
Capacity:	500 mL
Diameter:	127,6 mm
Sterilization method:	Ethylene Oxide
Shelf life:	60 months
CFU/g	N.A.
Sterility Assur. Level_ SAL	≤10 ⁻⁶
Weight/pc	Approx. 20,0 g
Tested in accordance w/	BS5452:1997(Adapted)
Height	60 mm
Graduation:	Scale in mL and FLOZ




STERILE **EO**

isento
Latex
free
isento
PVC
free


Nr and Revision Date:	45 -- 2023/01/18
CE Class:	Ila
CE mark:	CE1639
Compliance with:	MDD 93/42/EEC amended by 2007/47/EC

Applicable norms:	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 ;
GMDN:	42891 - General-purpose bowl, single-use

Important Notes: Plastic sleeve inside carton boxes

Level	Type	Dimension	Stamp	Labels
 1	1 Flexible peel-open pack	160x175mm		
 2	60 Plastic bag			labeled
 3	60 Carton box	586x388x317mm		labeled

Basic UDI	56056221200002HC
	EAN 1th level/nivel:05605622229409
	EAN 2th level/nivel:05605622429403
	EAN Carton Box/Caixa:05605622029405

Important Notes: -Not intended to be used for preparation of bone cement.

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 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	1664
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ISSUED BY: Quality Management Department, 2023/07/10

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