

Description: Surgical bowl 120ml

Composition:	PP pharmaceutical grade.
Latex:	Free
PVC:	Free
Re use:	No
Colour:	translucent
Capacity:	120 mL
Height:	35 mm
Diameter:	84,0 mm
Sterilization method:	Ethylene Oxide
Shelf life:	60 months
CFU/g	N.A.
Weight/pc	Approx. 7,5 g
Tested in accordance w/	BS5452:1977(adapted)

STERILE EO


isento
Latex
free

isento
PVC
free


Nr and Revision Date:	31 -- 2021/02/08
CE Class:	Ila
CE mark:	CE1639
Compliance with:	MDD 93/42/EEC amended by 2007/47/EC
Applicable norms:	BS 5452:1997-(partial compliance/cumprimento parcial) ; EN_ISO_13485.2016 ; EN_ISO_13485.2016_AC18 ; EN 556-1.2001_AC.2006 ; ISO_11135.2014 ; ISO_10993-1.2018 ; EN_ISO_11607_1 2017 ; EN_ISO_11607-2.2017 ; ISO_TS_16775.2014 ; ASTM_F1980_16 ; ISO_14644-1:2015 ; ISO_14698_1_2003 ; EN_ISO_14971.2012 ; EN_ISO_15223-1.2016 ; EN_1041.2008_A1.2013 ;

Important Notes: Plastic sleeve inside carton boxes

Level	Type	Dimension	Stamp	Labels
1	1 Flexible peel-open pack	134x140mm		
2	240 Carton box	780x380x315mm		labeled

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.

Waste instructions	No special requirements. The waste must be disposed according to local legal regulations for the disposable of medical waste.
Intended use	1. To temporarily hold organs or tissue 2. To hold, or for preparation and dilution of medicines, solutions or IV fluids to prepare medical devices such as catheters. 3. To hold aqueous, saline solutions or antiseptics for irrigation or disinfection of skin or mucosa, or for wound cleansing. 4. To hold and/or transfer instruments and/or other medical devices. Also to hold solutions for instrument cleansing during surgical procedures <i>Any modification of the product as presented or any use out of its intended use are not of the manufacturer responsibility.</i>

Non-harmonized symbols used in article labeling

MD

Medical Device

Environment - Packaging waste

Weight (gr) of packing material used in 100 pcs

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ISSUED BY: Quality Management Department, 2021/05/14