

DRQ 14/21 REV.00 2020/09/08

Description: Surgical bowl 250ml

Composition:	PP pharmaceutical grade.
Latex:	Free
PVC:	Free
Re use:	No
Colour:	translucent
Capacity:	250 mL
Height:	54 mm
Diameter:	101,9 mm
Sterilized by:	Ethylene Oxide
Shelf life:	60 months
CFU/g	N.A.
Weight/pc	Approx 13,0 g
Tested in accordance w/	BS5452:1977(adapted)

STERILE EO



isento
Latex
free

isento
PVC
free



Nr and Revision Date:	28 -- 2020/09/07
CE Class:	Ila
CE mark:	CE1639
Compliance with:	MDD 93/42/EEC amended by 2007/47/EC

Applicable norms:	EN ISO 13485:2016 ; EN 1041+A1:2013 ; EN ISO 11737-2:2009 ; EN 556-1:2008 ; EN ISO 14971:2012 ; EN 556-1:2001/AC:2006 ; ISO 11135:2014 ; EN ISO 15 223-1:2016 ; EN ISO 11 607-1:2017 ; ISO 10993-1:2018 ; EN ISO 11607-2:2017 ;
--------------------------	---

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

Level	Type	Dimension	Stamp	Labels
1	1 Flexible peel-open pack	134x140mm		
2	110 Carton box	580x382x311mm		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.
-------------------------	---

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	<ol style="list-style-type: none"> To temporarily hold organs or tissue 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 or antiseptics for irrigation or disinfection of skin or mucosa, or for wound cleansing. To hold and/or transfer instruments and/or other medical devices. Also to hold solutions for instrument cleansing during surgical procedures
---------------------	---

Environment - Packaging waste	Weight (gr) of packing material used in 100 pcs	1073
--------------------------------------	---	------

ISSUED BY: Quality Management Department, 2020/09/23