

Ref: 489-313

Technical Specifications

Brand:



Description: Surgical bowl

Composition:	PP pharmaceutical grade.
Latex:	Free
PVC:	Free
Re use:	No
Sterilizable by:	Ethylene Oxide
Colour:	translucent
Capacity:	120 mL
Height:	35 mm
Diameter:	88,0 mm
Shelf life:	120 months
CFU/g	<10^2
Graduation:	Internal in mL, Floz
Weight/pc	Approx. 7,3 g
Tested in accordance w/	BS5452:1977(adapted)

NON	Late fre	to isento PVC free	
	12 00°		
-	1100		

Nr and Revision Date:	32 2008/06/04
CE Class:	lla
CE mark:	CE0120
Directive:	MDD 93/42/EEC amended 2007/47/EC
Annlicable norms:	EN ISO 13485:2016 · EN ISO 11737-1:2006

Applicable norms: EN ISO 13485:2016; EN ISO 11737-1:2006; EN ISO 14971:2012; EN ISO 10993-1/AC:2010; ISO 1133-1:2011; ENISO11737-1:2006/AC:2009; ISO 16142-1:2016; EN ISO 15 223-1:2016;

Level		Туре	Dimension		Stamp	Labels
1	1120	Plastic bag				labeled
2	2240	Carton box	590x390x408r	nm		labeled

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 storage for medical devices shall
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 tissue 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

WASTE AND ENVIRONMENT REGULATIONS	Weight (gr) of packing material used in 100 pcs	57
-----------------------------------	---	----

ISSUED BY: Quality Management Department, 2020/02/20

CONFIDENTIAL: The information contained herein is confidential and belongs to Bastos Viegas, s.a. It is provided for specific purposes and in connection with established agreements. It is not permitted disclosure, reproduction, copying or distribution, in whole or in part, for other purposes or to any third parties.