

Ref: 460-001

Technical Specifications

Brand:



Description: Charlotte

Composition:	Polyester, Polypropylene nonwoven SB.
Latex:	Present
PVC:	Free
Re use:	No
Sterilizable by:	Ethylene Oxide
Colour:	green
Diameter:	500 mm
Shelf life:	120 months
CFU/g	<10^2
Fluorescence	conform
Size variation	±10 %



Nr and Revision Date:	5 2018/11/26
CE Class:	
CE mark:	CE
Directive:	MDD 93/42/EEC amended by 2007/47/EC
Applicable norms:	EN ISO 13485:2016; EN 1041+A1:2013; EN ISO 11737-1:2006; EN ISO 14971:2012;
	EN 1041:2008 ; ENISO11737-1:2006/AC:2009 ; EN ISO 15 223-1:2016 ;

Level		Туре	Dimension		Stamp	Labels
1	200	Carton box				labeled
2	7200	Carton box	1188x795x650mm branca			labeled

Important Notes:	Nr pcs/pack subjected to ± 3% variation				
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	Intended to be used by healthcare professionals to protect patients from possible contamination.				

WASTE AND ENVIRONMENT REGULATIONS	Weight (gr) of packing material used in 100 pcs	150

ISSUED BY: Quality Management Department, 2019/08/08

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