



Description: Dental roll nr 2

Composition:	Cotton.
Diameter:	10mm
Latex:	Free
PVC:	Free
Re use:	No
Sterilizable by:	Moist heat or EO
Length variation:	± 2 mm
Colour:	white
CFU/g	<10 ²
Extract colouring matter	conform
Foreign fibres	conform
Ether soluble substances	< 0,50 %
Water soluble substances	< 0,50 %
Sulphated ash	< 0,40 %
Fluorescence	conform
Loss on drying	< 8 %
Sinking time	< 10 s
pH (acidity/alkalinity)	conform
Surface-active substances	conform
Water-holding capacity	> 23 g/g
Size variation	N.A %
Size	3,6 cm



Nr and Revision Date:	6 -- 2016/08/31
CE Class:	I
CE mark:	CE
Directive:	MDD 93/42/EEC amended by 2007/47/EC

Applicable norms:	EN ISO 13485:2012 ; EN ISO 9001:2008 ; EN 1041+A1:2013 ; EN ISO 11737-1:2006 ; EN ISO 14971:2012 ; EN ISO 10993-1/AC:2010 ; EP:2012 ; EN 1041:2008 ; ENISO11737-1:2006/AC:2006 ; EN ISO 15 223-1:2016 ;
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Level	Type	Dimension	Stamp	Labels
1	600 Box 155x50x23mm			
2	27000 Carton box with 45 boxes			

Important Notes:	Nr pcs/pack subjected to ± 3% variation
Important Notes:	Hydrophilic cotton in accordance with Portuguese Pharmacopea 9.0 Monograph

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 devices storage shall apply.
Waste instructions	Waste: No special requirements. The waste must be disposed according to local legal regulations for the disposable of medical waste.
Intended use	For absorbing body fluids in oral cavity in dental care.

WASTE AND ENVIRONMENT REGULATIONS	Weight (gr) of packing material used in 100 pcs	0
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ISSUED BY: Quality Management Department, 2018/01/30