

Description: Tongue depressor

Composition:	Polystyrene.
Latex:	Free
PVC:	Free
Re use:	No
Colour:	translucent
Sterilized by:	Ethylene Oxide
Shelf life:	60 months
CFU/g	N.A.
Do not sterilize by	Moist heat

STERILE EO



isento  
Latex  
free

isento  
PVC  
free



Nr and Revision Date:	18 -- 2020/10/26
CE Class:	I Steril
CE mark:	CE1639
Compliance with:	MDD 93/42/EEC amended by 2007/47/EC

Applicable norms: 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: Adult size in one end / Child size in other end

Level	Type	Dimension	Stamp	Labels
1	1 Flexible peel-open pack	50x190mm		
2	90 Folding-box	155x155x186mm		labeled
3	1800 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: Intended to displace the tongue to facilitate examination of the surrounding organs and tissues.

Any modification of the product as presented or any use out of its intended use are not of the manufacturer responsibility.

Environment - Packaging waste	Weight (gr) of packing material used in 100 pcs	261
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ISSUED BY: Quality Management Department, 2021/03/08