

Art. No.	388993 (098725)
NAME OF PRODUCT	Wooden tongue depressor
DESCRIPTION OF PRODUCT	Wooden tongue depressor 15cm
	Size:150×18×1.6mm
	Latex status : Latex-free
	Remark: Specifications pls. refer to attachments I, II
Classification (MDD, Annex IX)	Class I Rule 5
INTENDED USE OF PRODUCT	To be assistant tool for examining nonnasality

APPLICABLE HARMONIZED STANDARD	
Standard No.	File Title
MDD 93/42/EEC amended by Directive 2007/47/EC	Medical Device Directive: Council Directive 93/42 EEC of 14 June 1993 concerning medical devices
EN ISO 13485:2016	Medical devices-Quality management systems-Requirements for regulatory purposes
EN ISO 14971:2012	Medical devices-Application of risk management to medical devices
EN ISO 10993-5: 1999	Biological evaluation of medical devices-Part 5: Test for cytotoxicity
EN ISO 10993-10: 2002	Biological evaluation of the medical devices-Part 10: Tests for irritation and skin sensitization
EN ISO 15223-1:2016	Medical devices-Symbols to be used with medical device labels, labeling and information to be supplied
EN 1041:2008	Information supplied by the manufacturer of medical devices

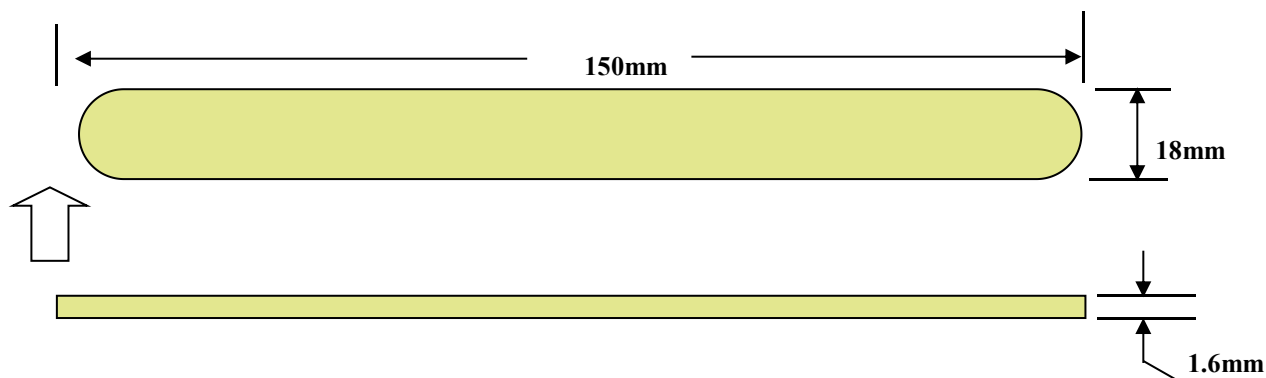
RAW MATERIAL		
CODE FOR THE ENCLOSED	RAW MATERIAL	ADDITIONAL INFORMATION
RAW MATERIAL SPECIFICATION	Wooden applicator	Birch
	Closure tape	PP transparent tape
	Inner box	Cardboard Weight: 450g/m ²
	Transport carton	Double Wall Corrugated Fibreboard Carton quality:A+B flute

QUALITY SPECIFICATION OF THE PRODUCT			
CHARACTERISTIC	TARGET VALUE	QUALITY TOLERANCES	TEST METHOD
FINISHED SIZE	Lenght=150mm	+/- 1mm	Measuring
	Width=18mm	+/- 1mm	Measuring
	Thickness=1.6mm	+/- 0.1mm	Measuring

DESCRIPTION OF THE PACKAGING SYSTEM																											
<table border="1"> <tr> <th colspan="3">PACKING</th> </tr> <tr> <td colspan="3">100pcs/box, 5000pcs/ctn</td> </tr> <tr> <th colspan="3">BOX SIZE (cm)</th> </tr> <tr> <td>L</td> <td>W</td> <td>H</td> </tr> <tr> <td>15.2</td> <td>8.4</td> <td>3.9</td> </tr> <tr> <th colspan="3">CARTON SIZE (cm)</th> </tr> <tr> <td>L</td> <td>W</td> <td>H</td> </tr> <tr> <td>44.5</td> <td>32</td> <td>21</td> </tr> </table>				PACKING			100pcs/box, 5000pcs/ctn			BOX SIZE (cm)			L	W	H	15.2	8.4	3.9	CARTON SIZE (cm)			L	W	H	44.5	32	21
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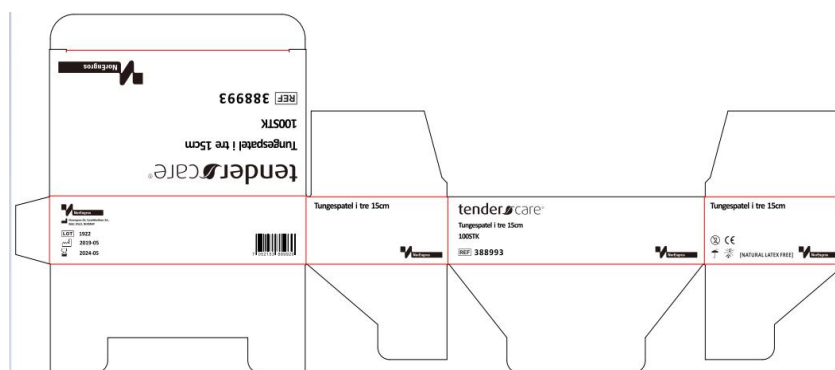
Wooden tongue depressor

Attachment I



Printing / label

inner box



out carton

<p>tendercare®</p> <p>☒ CE ☂ ☀ [NATURAL LATEX FREE] ♻️</p>	<p>tendercare®</p> <p>Varenummer: 388993</p> <p>LOT 1922</p> <p>Tungespatel i tre 15cm</p> <p>5000STK (50x100)</p> <p>2019-05</p> <p>2024-05</p> <p>7 105215 7188993 2</p> <p>Net weight: 13.5KG</p> <p>Gross weight: 14.5KG</p> <p>Norengros</p> <p>Norengros AS, Fyrstikkalleen 3A, 0661 OSLO, NORWAY</p> <p>Made In China</p>
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