

Art. No.	388992(361308)
NAME OF PRODUCT	Wooden applicator
DESCRIPTION OF PRODUCT	Wooden applicator with small head
	Size:150×2.2mm
	Latex status : Latex-free
	Remark: Specifications pls. refer to attachments I, II
Classification (MDD, Annex IX)	Class I Rule 4
INTENDED USE OF PRODUCT	To be a testing tool for examining in the hospital or laboratory

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 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

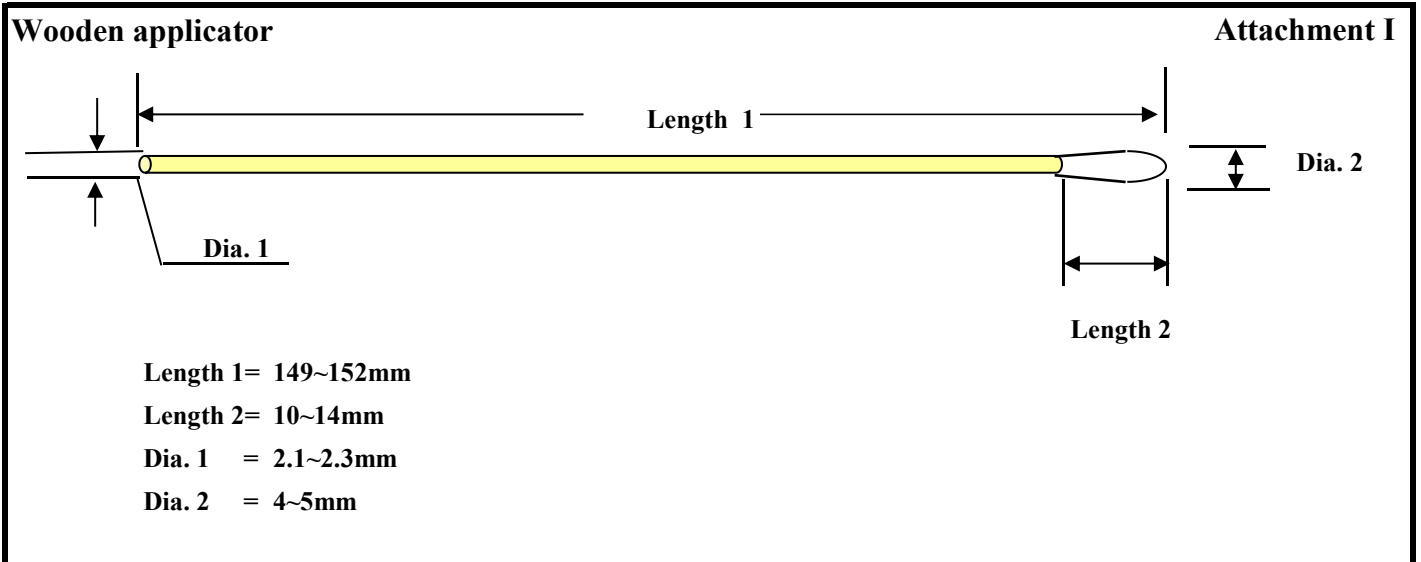
CODE FOR THE ENCLOSED	RAW MATERIAL	ADDITIONAL INFORMATION
RAW MATERIAL SPECIFICATION	Wooden applicator	Birch
	Cotton head	Nature cotton
	Closure tape	PP transparent tape
	Inner zip bag	PE, transparent
	Inner box	Single Wall Corrugated Fibreboard Weight: 450g/m ²
	Transport carton	Double Wall Corrugated Fibreboard Carton quality:A+B flute material

QUALITY SPECIFICATION OF THE PRODUCT

CHARACTERISTIC	TARGET VALUE	QUALITY TOLERANCES	TEST METHOD
FINISHED SIZE	Stick=148(length)×2.2(Dia.)mm	+/- 1mm(length), +/- 0.1mm(Dia.)	Measuring
	Head=12(length)×4.5(Dia.)mm	+/-2mm(length,), +/- 0.5mm(Dia.)	Measuring
	Total length=150mm	149~152mm	Measuring

DESCRIPTION OF THE PACKAGING SYSTEM

PACKING	Diagram	
100pcs/bag, 24bags/box, 10boxes/ctn		
Zip PE BAG SIZE (cm)		
L W T		
18 11 60mic		
BOX SIZE (cm)		
L W H		
31.5 17 9		
CARTON SIZE (cm)		
L W H		
46 33.5 36		



Printing/label **Attachment II**

inner bag printing

tendercare®
 Bomullspinne usteril 15cm
 100STK
 Varenummer: 388992

LOT 1922
 2019-05
 2024-05

CE [NATURAL LATEX FREE]

NorEngros
 Norengros AS, Fyrstikkalleen 3A,
 0661 OSLO, NORWAY

7 052153 889925

inner box label

tendercare®
 Bomullspinne usteril 15cm
 2400STK (24x100STK)
 Varenummer: 388992

LOT 1922
 2019-05
 2024-05

CE [NATURAL LATEX FREE]

NorEngros
 Norengros AS, Fyrstikkalleen 3A,
 0661 OSLO, NORWAY

7 052153 889925

out box printing

tendercare®

Net weight: 9.6KG
 Gross weight: 10.3KG

CE [NATURAL LATEX FREE]

tendercare®
 Varenummer: 388992
 Bomullspinne usteril 15cm
 24000STK (10x24x100STK)

LOT 1922
 2019-05
 2024-05

7 052153 889924

NorEngros
 Norengros AS, Fyrstikkalleen 3A,
 0661 OSLO, NORWAY
 Made in China