

PRODUCTION SPECIFICATION

Art. No.	388991 (242331)
NAME OF PRODUCT	Wooden applicator
DESCRIPTION OF PRODUCT	Wooden applicator with medium head , EO pack
	Size:150×2.5mm
	Latex status : Latex-free
	Shelf life: 5 years
	Remark: Specifications pls. refer to attachments I, II
Classification (MDD, Annex IX)	Class Is 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
EN ISO 10993-5: 2009	Biological evaluation of medical devices-Part 5: Test for cytotoxicity
EN ISO 10993-10: 2010	Biological evaluation of the medical devices-Part 10: Tests for irritation and skin sensitization
ISO 11135:2014	Sterilization of health-care products-Ethylene oxide-Requirements for the development, validation and routine control of a sterilization process for medical device
EN ISO14937:2010	Sterilization of health care products-General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices
EN ISO11607-1:2009+A1:2014	Package of Terminal Sterilization Devices --- Part 1, Request of Material, Sterilization Inter layer and package system
EN ISO11607-2:2006+A1:2014	Package of Terminal Sterilization Devices --- Part 2, Authentication Request of Composition, Sealing and Assembling process
EN ISO 11737-1: 2006	Sterilization of medical devices-Microbiological methods-Part 1: Determination of a population of microorganisms on products
MEDDEV 2.4/1REV.9:2010	Guidelines relating to the application of the council directive 93/42/EEC on medical device
MEDDEV 2.7.1 Rev4:2016	CLINICAL EVALUATION:A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES UNDER DIRECTIVES 93/42/EEC and 90/385/EEC

RAW MATERIAL

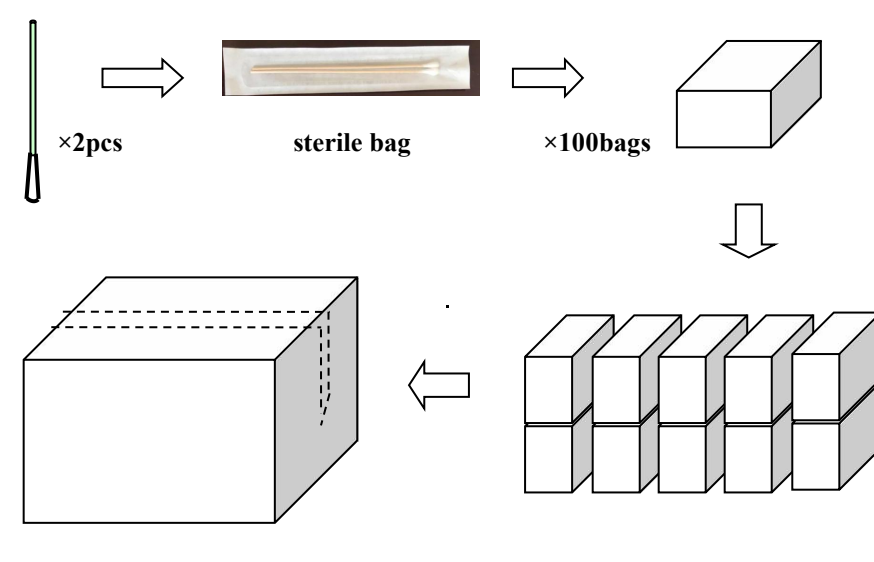
CODE FOR THE ENCLOSED	RAW MATERIAL	ADDITIONAL INFORMATION
RAW MATERIAL SPECIFICATION	Wooden applicator	Birch
	Cotton head	Nature cotton
	Closure tape	PP transparent tape
	EO pouch	Tissue with PE film, white/transparent
	Inner box	Single Wall Corrugated Fibreboard Weight: 450g/m ²
	Transport carton	Double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

QUALITY SPECIFICATION OF THE PRODUCT

CHARACTERISTIC	TARGET VALUE	QUALITY TOLERANCES	TEST METHOD
FINISHED SIZE	Stick=148(length)×2.5(Dia.)mm	+/- 1mm(length), +/- 0.1mm(Dia.)	Measuring
	Head=12(length)×5.5(Dia.)mm	+/-2mm(length,), +/- 0.5mm(Dia.)	Measuring
	Total length=150mm	149~152mm	Measuring

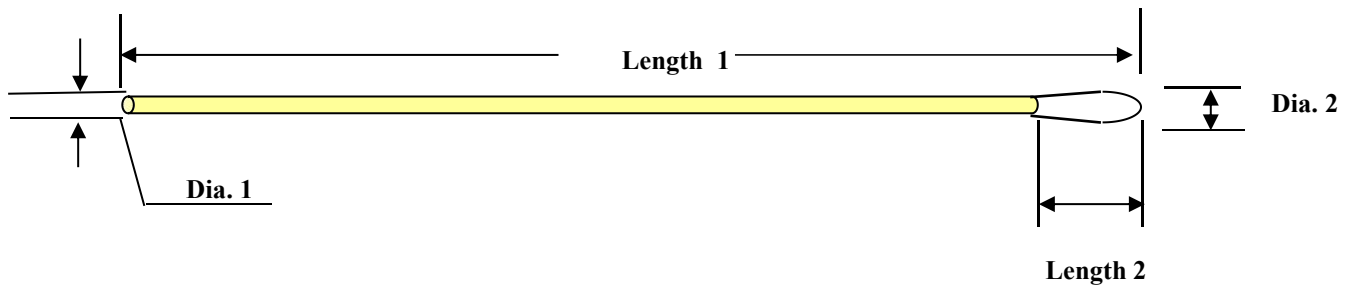
DESCRIPTION OF THE PACKAGING SYSTEM

PACKING		
2pcs/sterile pack, 100packs/box, 10boxes/ctn		
STERILE BAG SIZE (cm)		
L	W	T
19.6	3	--
BOX SIZE (cm)		
L	W	H
19.5	13	5.5
CARTON SIZE (cm)		
L	W	H
53	27	20



Wooden applicator

Attachment I

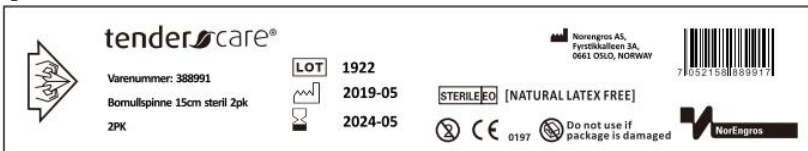


- Length 1= 149~152mm
- Length 2= 10~14mm
- Dia. 1 = 2.4~2.6mm
- Dia. 2 = 5~6mm

Printing/label

Attachment II

pouch



inner box label



out carton

