

<b>Art. No.</b>	<b>254166</b>
NAME OF PRODUCT	Forceps, sterilized, green
DESCRIPTION OF PRODUCT	12.8cm, green Remark: Specifications pls. refer to attachments I, II
Classification (MDD, Annex IX)	Class Is Rule 1
INTENDED USE OF PRODUCT	Tool for reaching

**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
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 ISO 14937:2010	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 ISO 11607-1:2009+A1:2014	Package of Terminal Sterilization Devices --- Part 1, Request of Material, Sterilization Inter layer and package system
EN ISO 11607-2:2006+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/REV.9:2010	Guidelines relating to the application of the council directive 93/42/EEC on medical device

**RAW MATERIAL**

CODE FOR THE ENCLOSED	RAW MATERIAL	ADDITIONAL INFORMATION
RAW MATERIAL SPECIFICATION	Forceps	PS, green
	Closure tape	PP transparent tape
	Inner box	Single Wall Corrugated Fibreboard ,white Weight: 450g/m <sup>2</sup>
	Transport carton	Double Wall Corrugated Fibreboard ,white Weight: 600g/m <sup>2</sup>

**QUALITY SPECIFICATION OF THE PRODUCT**

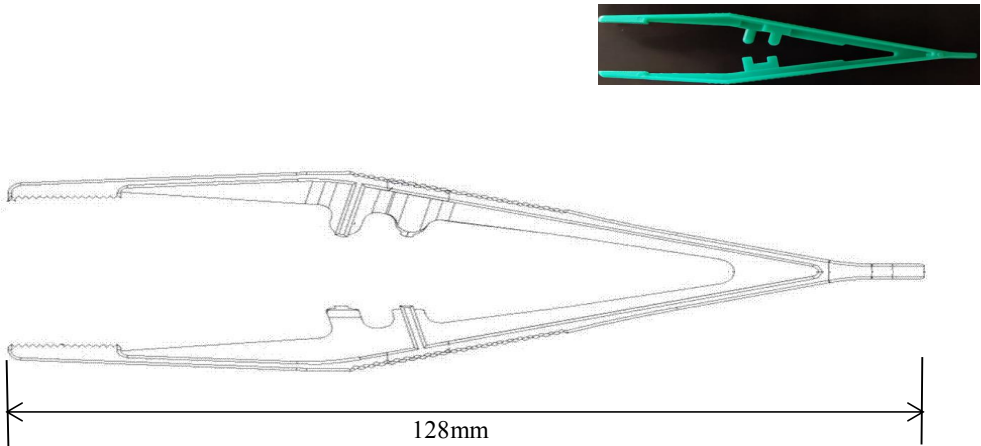
CHARACTERISTIC	TARGET VALUE	QUALITY TOLERANCES	TEST METHOD
FINISHED SIZE	length=12.8cm	+/- 1mm	Measuring
	width=2.8cm	+/- 1mm	Measuring
PRODUCTION WEIGHT	Total weight=5.6g/pc	+/- 5%	Weighing

**DESCRIPTION OF THE PACKAGING SYSTEM**

PACKING			
50pcs/box, 300pcs/ctn			
POUCH BAG SIZE (cm)			
L      W      T			
18      6.5      ---			
BOX SIZE (cm)			
L      W      H			
20      18      11			
CARTON SIZE (cm)			
L      W      H			
37.5      34      22			

Forceps

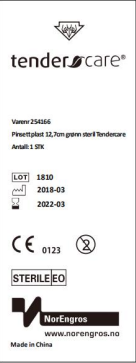
Attachment I



Printing/Label

Attachment II

inner pouch printing



inner box label



out carton

