

Technical Datasheet

EN ISO 13485 certified		
Article - No:	09-511-5017	Revision: 7
Remarks	Complies with the requirement of MDD directive 93/42/EEC, class IIa: transient use as surgical invasive product is feasible.	single use only

Specification

Product	Culture swab, without transport medium, flexible PS stick with viscose tip, color code white, np pcr ready, sterile R, CE/IVD
Classification	CE/IVD
Dimensions	tube:
	length: 152,00 mm (+/- 5 mm)
	outer diameter: 11,50 mm (+/- 0,5 mm)
	inner diameter: 10,00 mm (+/- 0,5 mm)
	plug:
	length: 26,00 mm (+/- 0,2 mm)
	outer diameter: 12,00 mm (+/- 0,5 mm)
	stick:
	length: 150,00 mm (+/- 3 mm)
	diameter: 2,50 mm (+/- 0,2 mm)
diameter tip: 5,00 mm (+/- 1 mm)	
total length of tube and plug: 174,00 mm (+/- 3 mm)	
Material Characteristics	tube: polypropylene (PP)
	plug: polyethylene (PE)
	swab: polysterene (PS)
	tip of swab: viscose (VI)
Product Characteristics	biologically inert
	physiologically harmless
	no heavy metals according to EC/94/62
	Food contact: raw material in compliance with regulation EC 1935/2004
	free of detectable phthalate acc. to REACH regulation
	free of latex
Purity Grade	free of PCR inhibitors



Technical Datasheet

	free of human DNA
	free of RNase and DNase
	free of pyrogens
Sterilisation Process	radiation sterilization SAL 10-6
Shelf - Life	36 months at controlled storage conditions
Packaging	pcs per carton: 2.000
	pcs per pallet: 48.000
	pcs per dsp case: 500
Storage	dry condition: 40%-60% rel. humidity
	bags / cases orig. closed
	storage temp. +10°C to max. +30°C
	pal. not stackable
Approved by nerbe plus quality department	