

# Technical Datasheet

Date: 05.02.20

Page 1 of 2

EN ISO 13485 certified		
<b>Article - No:</b>	<b>09-511-5008</b>	<b>Revision: 8</b>
<b>Remarks</b>	<b>Complies with the requirement of MDD directive 93/42/EEC, class IIa: transient use as surgical invasive product is feasible.</b>	<b>single use only</b>

## Specification

<b>Product</b>	Culture swab, without transport medium, flexible PP stick with viscose tip, color code white, single peel-pack, np pcr ready, sterile R, CE/IVD															
<b>Classification</b>	CE/IVD															
<b>Dimensions</b>	<table border="1"> <tr><td>tube:</td></tr> <tr><td>length: 145,00 mm (+/- 0,2 mm)</td></tr> <tr><td>outer diameter: 12,00 mm (+/- 0,2 mm)</td></tr> <tr><td>inner diameter: 10,70 mm (+/- 0,2 mm)</td></tr> <tr><td>plug:</td></tr> <tr><td>length: 20,00 mm (+/- 0,2 mm)</td></tr> <tr><td>outer diameter: 12,00 mm (+/- 0,2 mm)</td></tr> <tr><td>stick:</td></tr> <tr><td>length: 130,00 mm (+/- 0,2 mm)</td></tr> <tr><td>diameter: 2,50 mm (+/- 0,2 mm)</td></tr> <tr><td>diameter tip: 4,00 mm (+/- 0,2 mm)</td></tr> <tr><td>peelpack:</td></tr> <tr><td>length: 210,00 mm (+/- 0,2 mm)</td></tr> <tr><td>width: 38,00 mm (+/- 0,2 mm)</td></tr> <tr><td>total length of tube and plug: 165,00 mm (+/- 0,2 mm)</td></tr> </table>	tube:	length: 145,00 mm (+/- 0,2 mm)	outer diameter: 12,00 mm (+/- 0,2 mm)	inner diameter: 10,70 mm (+/- 0,2 mm)	plug:	length: 20,00 mm (+/- 0,2 mm)	outer diameter: 12,00 mm (+/- 0,2 mm)	stick:	length: 130,00 mm (+/- 0,2 mm)	diameter: 2,50 mm (+/- 0,2 mm)	diameter tip: 4,00 mm (+/- 0,2 mm)	peelpack:	length: 210,00 mm (+/- 0,2 mm)	width: 38,00 mm (+/- 0,2 mm)	total length of tube and plug: 165,00 mm (+/- 0,2 mm)
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<b>Material Characteristics</b>	<table border="1"> <tr><td>tube: polypropylene (PP)</td></tr> <tr><td>plug: polyethylene (PE)</td></tr> <tr><td>swab: polypropylene (PP)</td></tr> <tr><td>tip of swab: viscose (VI)</td></tr> </table>	tube: polypropylene (PP)	plug: polyethylene (PE)	swab: polypropylene (PP)	tip of swab: viscose (VI)											
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Page 2 of 2

	free of detectable phthalate acc. to REACH regulation
	free of latex
<b>Purity Grade</b>	free of PCR inhibitors
	free of human DNA
	free of RNase and DNase
	free of pyrogens
<b>Sterilisation Process</b>	radiation sterilization SAL 10-6
<b>Shelf - Life</b>	36 months at controlled storage conditions
<b>Packaging</b>	pcs per carton: 2.000
	pcs per pallet: 16.000
	pcs per dsp case: 100
<b>Storage</b>	dry condition: 40%-60% rel. humidity
	bags / cases orig. closed
	storage temp. +2°C to max. +30°C
	pal. not stackable
<b>Approved by nerbe plus quality department</b>	