

Technical Datasheet

Date: 14.02.17

Page 1 of 2



EN ISO 13485 certified

		EN ISO certified
Article - No:	09-551-8066	Revision: 2
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	Transport swab with amies medium, flexible PS stick with viscose tip, color code blue, single peel-pack, np pcr ready, sterile R, CE/IVD															
Classification	CE/IVD															
Dimensions	<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: 150,00 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: 38,00 mm (+/- 0,2 mm)</td></tr> <tr><td>width: 210,00 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: 150,00 mm (+/- 0,2 mm)	diameter: 2,50 mm (+/- 0,2 mm)	diameter tip: 4,00 mm (+/- 0,2 mm)	peelpack:	length: 38,00 mm (+/- 0,2 mm)	width: 210,00 mm (+/- 0,2 mm)	total length of tube and plug: 165,00 mm (+/- 0,2 mm)
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: 150,00 mm (+/- 0,2 mm)																
diameter: 2,50 mm (+/- 0,2 mm)																
diameter tip: 4,00 mm (+/- 0,2 mm)																
peelpack:																
length: 38,00 mm (+/- 0,2 mm)																
width: 210,00 mm (+/- 0,2 mm)																
total length of tube and plug: 165,00 mm (+/- 0,2 mm)																
Material Characteristics	<table border="1"> <tr><td>tube: polypropylene (PP)</td></tr> <tr><td>plug: polyethylene (PE)</td></tr> <tr><td>swab: polysterene (PS)</td></tr> <tr><td>tip of swab: viscose (VI)</td></tr> </table>	tube: polypropylene (PP)	plug: polyethylene (PE)	swab: polysterene (PS)	tip of swab: viscose (VI)											
tube: polypropylene (PP)																
plug: polyethylene (PE)																
swab: polysterene (PS)																
tip of swab: viscose (VI)																
Product Characteristics	<table border="1"> <tr><td>biologically inert</td></tr> <tr><td>physiologically harmless</td></tr> <tr><td>no heavy metals according to EC/94/62</td></tr> <tr><td>Food contact: raw material in compliance with regulation EC 1935/2004</td></tr> <tr><td>free of detectable phthalate acc. to REACH regulation</td></tr> <tr><td>free of latex</td></tr> </table>	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									
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	<table border="1"> <tr><td>free of PCR inhibitors</td></tr> <tr><td>free of human DNA</td></tr> <tr><td>free of RNase and DNase</td></tr> </table>	free of PCR inhibitors	free of human DNA	free of RNase and DNase												
free of PCR inhibitors																
free of human DNA																
free of RNase and DNase																

nerbe plus GmbH
Daimlerstrasse 3
21423 Winsen/Germany
Tel: +49 (0)4171 7849 0
Fax: +49 (0)4171 645 45

E-Mail: info@nerbe-plus.de
Web: www.nerbe-plus.de
Amtsgericht Lüneburg
HRB 110004
USt-IdNr. DE 11681 7171

Deutsche Postbank AG
BLZ 200 100 20
Kto. 2891 87204
IBAN DE37 2001 0020 0289 1872 04
SWIFT / BIC PBNKDEFFXXX

Commerzbank AG
BLZ 200 800 00
Kto. 1926 47000
IBAN DE43 2008 0000 0192 6470 00
SWIFT / BIC DRESDEFF200

GmbH Gesellschafter Geschäftsführer: Jürgen F. Nerbe | Philipp J.F. Nerbe

Gläubiger IdNr.: DE33ZZZ00000308514



Technical Datasheet

Date: 14.02.17

Page 2 of 2

	free of pyrogens
Sterilisation Process	radiation sterilization SAL 10-6
Shelf - Life	30 months at controlled storage conditions
Packaging	pcs per carton: 1.200
	pcs per pallet: 19.200
	pcs per dsp case: 150
Minimum order qty.	1.200 pcs
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	

