

# PRODUCT SPECIFICATION

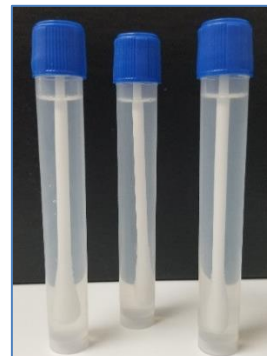
Product PN 10498305 (125 pk) & 10498306 (500 pk)

Mod. 984

Description BUFFER SWABS

Rev. 02

## Buffer Swabs



<b>PRODUCT DESCRIPTION</b>	<p>SWAB BUFFER 4ml 125/PK (10498305) and 500/PK (10498306)</p> <p>Buffer Swabs are used for the collection of surface contamination from flat or convoluted surfaces prior to transport to a laboratory for culture and enumeration. Buffer swabs contain no bacteriostatic or bactericidal compounds and cannot suppress the action of detergents.</p>
<b>MANUFACTURER NAME</b>	<p><b>GVS North America</b>  <b>63 Community Drive</b>  <b>Sanford, Me 04073</b>  Phone: +1.866.736.1250  eMail: <a href="mailto:CustomerCareGVSL@gvs.com">CustomerCareGVSL@gvs.com</a> - Website: <a href="http://www.gvs.com">www.gvs.com</a></p>
<b>INTENDED USE / APPLICATION</b>	<p>Buffer Swabs are used for the collection of surface contamination from flat or convoluted surfaces prior to transport to a laboratory for culture and enumeration.</p>
<b>MATERIALS</b>	<p><b>Media:</b> Buffer Solution</p> <p><b>Color:</b> Clear liquid</p> <p><b>Tube:</b> clear polypropylene  <b>Screw Cap:</b> Blue polyethylene with silicone washer  <b>Swab:</b> white cotton</p> <p><b>Regulatory Documentation Required:</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Biocompatibility according ISO 10993-1</li> <li><input type="checkbox"/> IMDS</li> <li><input checked="" type="checkbox"/> RoHS, directive 2002/95/CE</li> <li><input type="checkbox"/> BSE/TSE, directive 2003/32/</li> <li><input type="checkbox"/> DEHP plasticizer Free and latex free</li> <li><input type="checkbox"/> Aging</li> <li><input checked="" type="checkbox"/> Reach 1907/2006/CE (hazardous substances regulation)</li> <li><input type="checkbox"/> Dir. 67/548/CE and Reg. 1272/2008/CE (medical sector dangerous substances)</li> <li><input checked="" type="checkbox"/> Conflict minerals</li> </ul>

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<b>PRODUCT CHARACTERISTIC</b>	<p>Clear buffer dispensed in self standing, round bottomed capped plastic vials. The cotton swab is secured inside the screw cap</p> <p><b>Physical Dimensions:</b>  <b>Vial:</b> 12 x 84 mm  <b>Cap:</b> 14 x 13.25 mm polyethylene with silicone washer  <b>Swab:</b> 78mm long</p> <p><b>Volume/tube:</b> 3.6 – 4.2 ml  <b>Incubation Temperature Range:</b> From 33°C to 37°C  <b>Storage temperature Range:</b> From 2°C to 8°C</p> <p><b>Biological:</b>  Product is sold sterilized.  <b>Toxicity:</b> See SDS for further information.</p>
<b>INSTRUCTIONS</b>  <b>WARNINGS</b>	<p>Product is temperature sensitive.  Store at recommended temperature.</p>
<b>PRODUCT SHELF LIFE</b>	<p>12 months when stored properly</p>
<b>STERILIZATION</b>	<p>Product is sold sterilized.</p>
<b>PACKAGING AND LABELLING</b>	<ol style="list-style-type: none"> <li>Vials are placed in box containing an insert.  PN 10498305 contains 125 vials.  PN 10498306 contains 500 vials.</li> <li>Box is labeled and then shrink-wrapped.</li> </ol> <p><b>LABEL:</b></p> 

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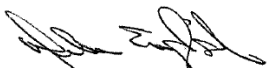
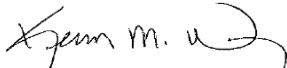
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CERTIFICATE OF COMPLIANCE	With each shipment, GVS NA will provide the CoC with item number, lot number and expiration date. The Quality management system is in compliance with ISO 9001.																																						
VISUAL REQUIREMENTS	<p><b>Visual acceptance requirements apply when inspected under below conditions:</b> <b>Magnification:</b> none <b>Light type:</b> normal room lighting</p> <table><tr><th colspan="3">Acceptance Requirement</th><th>Sampling Plan</th></tr><tr><td>1</td><td>Color – Clear liquid</td><td>all</td><td rowspan="2">100%</td></tr><tr><td>2</td><td>Vial appearance – no misshapen or leaking vials. Each vial contains a swab</td><td>none</td></tr></table>			Acceptance Requirement			Sampling Plan	1	Color – Clear liquid	all	100%	2	Vial appearance – no misshapen or leaking vials. Each vial contains a swab	none																									
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<p>This material specification describes the properties of product above indicated. This document contains general requirements, material description, drawing references, defect specification, biological material requirements.</p>																																							

## REVISIONS AND APPROVALS:

DATE	REV.	REASON FOR CHANGE	ISSUED AND CONTROLLED BY: (name /function and signature)	APPROVED BY: (name /function and signature)
11/7/18	0	Initial release	Debra English/Manager Biochemistry Applications 	Kevin Wrigley/Director, Quality 

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## *Customer Approval:*

We accept this material specification as a part of the agreed terms of delivery

Company name \_\_\_\_\_

Approved by: \_\_\_\_\_  
(Name, Function) (Signature)

Date \_\_\_\_\_  
(Company stamp)

*Please send back this document signed for approval. If we will not receive this specification signed, we consider the first order placed as implicit approval.*