PRODUCT SPECIFICATION

Product PN *10498407*

Mod. 984

Rev. 02

Description Hygiene SwabCheck 25/pk

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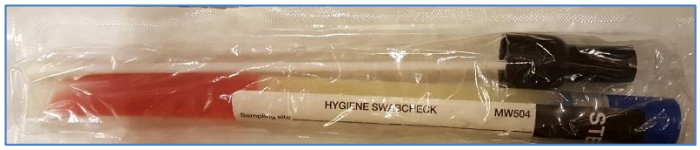

PRODUCT DESCRIPTION	Hygiene SwabCheck 25/pk A ready to use test for the detection of high levels of microorganisms at a sampling site.
MANUFACTURER NAME	**GVS North America** **63 Community Drive** **Sanford, Me 04073** Phone: +1.866.736.1250 eMail: CustomerCareGVSLS@gvs.com - Website: www.gvs.com
INTENDED USE / APPLICATION	The requirements for “cleanliness” in industry can vary greatly depending on the circumstances involved. However, in most areas a high level of contamination is undesirable and can lead to production problems. Monitoring of cleaning down procedures and working levels of contamination is simplified by the use of the Hygiene SwabCheck. Based on traditional microbiological test, Hygiene SwabCheck indicated gross contamination at a sampling site by a simple color change from red to yellow within 4 hours of inoculation and incubation.
MATERIALS	**Culture Media:** Hygiene SwabCheck media **Culture Media Color:** Red **Swab Tube:** 15 cm **Swab:** Black-capped swab **Regulatory Documentation Required:** ☐Biocompatibility according ISO 10993-1 ☐IMDS ☒Rohs, directive 2002/95/CE ☐BSE/TSE, directive 2003/32/ ☐DEHP plasticizer Free and latex free ☐Aging ☒Reach 1907/2006/CE (hazardous substances regulation) ☐Dir. 67/548/CE and Reg. 1272/2008/CE (medical sector dangerous substances) ☒Conflict minerals

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PRODUCT CHARACTERISTIC	**Self-contained swab device consisting of (1) a black capped swab and (2) a tube containing a red-colored gel media.** **Physical:** **Tube:** 15 cm **Swab:** black capped swab **Incubation Temperature Range:** 35ºC ± 2°C **Storage temperature Range:** From 5°C to 25°C **Biological:** Product is sold sterilized. **Toxicity:** See SDS for further information.
INSTRUCTIONS **WARNINGS**	Liquid media is temperature sensitive. Store at recommended temperature. **DO NOT FREEZE**.
PRODUCT SHELF LIFE	12 months when stored properly
STERILIZATION	Product is sold sterilized.
PACKAGING AND LABELLING	25 devices placed in a box containing an insert. The box is labeled**.** Label contains: Item Description, item code, lot number, qty and Exp Date.
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	***Visual acceptance requirements apply when inspected under below conditions:*** **Magnification:** none **Light type:** normal room lighting

	Liquid Media Acceptance Requirement		Sampling Plan
1	Color – red colored gel	all	100%
2	Tube appearance – no misshapen tube.	none	
3	Package contains swab & tube of red-colored gel media	all	

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PERFORMANCE REQUIREMENTS

Liquid Media Acceptance Requirement			Sampling Plan
	Parameter	**Specification**	
1	Performance: qualitative	Color change: red to yellow	ISO 11133:2014
2	Test Organisms, Positive control	*E. coli* NCTC 9001 *Streptococcus faecalis* NCTC 0775 *Proteus mirabilis* NCTC 11938 *Staphylococcus aureus* NCTC 8532	ISO 11133:2014
3	Sterility	Zero Growth	ISO 11133:2014
4	Media Color - Negative	red	ISO 11133:2014
5	Media Color - Positive	yellow	ISO 11133:2014
6	Incubation	35°C ± 2°C for 4-12 hours	ISO 11133:2014

This material specification describes the properties of product above indicated.
This document contains general requirements, material description, drawing references, defect specification, biological material requirements.

REVISIONS AND APPROVALS:

DATE	REV.	*REASON FOR CHANGE*	ISSUED AND CONTROLLED BY: (name /function and signature)	APPROVED BY: (name /function and signature)
11/18/2019	0	Initial release	Debra English/Manager Biochemistry Applications	Kevin Wrigley/Director, Quality

CustomerApproval:

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Description **Hygiene SwabCheck 25/pk**

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.