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Contact[™] Surface Sampling, *<u>Two Samples per Location</u>*

Cat. #: TD100 / MD300

2023 USP <797> Section 6.3 Monitoring Surfaces for Viable Particles

For additional Cultivate[™] directions for use and test logs, go to <u>www.parasolmed.com/cultivate/cultivate-resources</u>

Person(s) Collecting Samples : _____

Parasol Medical LLC.

Person(s) Identifying / Reading Results: _____

Additional Information: _____

Person(s) Documenting Results: _____

Test Type / Description: _____

				SAMPLE 1 - TSA Growth Media 2023 USP <797> 30-35°C for no less than 48 hr		SAMPLE 2 - TSA or MEA Growth Media 2023 USP <797> 20-25°C for no less than 5 days			RESULTS Action levels are for each samples			
Sample No.	Sample Date	Sample Location Decription Must be described in facility SOPs	Sample Location ISO Class	Interval Start Date	Growth After Incubation (Y or N)	CFU Count	Growth Media	Interval Start Date	Growth After Incubation (Y or N)	CFU Count	Test Results	Genus Classification if CFU count exceeds action levels
							TSA MEA				PASS	
							TSA MEA				PASS	
							TSA MEA				PASS	
							TSA				PASS	
							TSA MEA				PASS	
							TSA MEA				PASS	
							TSA MEA				PASS	
							TSA MEA				PASS	
						<u> </u>	TSA MEA				PASS	
							TSA				PASS	

PRODUCT INFORMATION						
Component No.: T-D100 List all if using multiple lots, identify	Media Type: TSA with L&T, Sterile which Sample No. are associated with each lot	Media Manufacture: Parasol Medical				
Media Lot. #: Media Exp.Date:						
Component No.: M-D300 List all if using multiple lots, identify	Media Type: MEA with L&T, Sterile which Sample No. are associated with each lot	Media Manufacture: Parasol Medical				
Media Lot. #: Media Exp.Date:						
Check box to confirm you collected certificate of analysis (CoA) for growth media. Keep a copy of the CoA(s) on file. To download a copy, visit <u>www.parasolmed.com/cultivate/cultivate-resources</u>						

CORRECTIVE ACTION SUMMARY / COMMENTS:	Surface Sampling Action Levels, per 2023 USP <797> ¹				
	ISO Class	Surface Sampling Action Levels (cfu/device or swab)			
	5	>3			
	7	>5			
	8	>50			
	Action le	vels are based on the total cfu count for both sides of paddle			