


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

 21371 Accredited to ISO/IEC 17025:2017	Swann-Morton (Microbiological Laboratory Services) Limited	
	Issue No: 003 Issue date: 12 July 2024	
	Penn Works Owlerton Green Sheffield South Yorkshire S6 2BJ	Contact: Darren Hall Tel: +44 (0)114 234 4231 E-Mail: darrenhall@swann-morton.com Website: www.swann-morton.com/pages/swannmorton_micro.php
Testing performed by the Organisation at the locations specified below		

Locations covered by the organisation and their relevant activities

Laboratory locations:

Location details		Activity	Location code
Address Penn Works Owlerton Green Sheffield South Yorkshire S6 2BJ	Local contact Mr Darren Hall	Testing: Microbiological and physical Bacterial endotoxin test Client site work	A

Site activities performed away from the locations listed above:

Location details		Activity	Location code
Medical Device and Pharmaceutical manufacturing and re-processing premises, associated clean rooms and workplace environments		Sampling of air and surfaces at clients' premises Testing air quality for physical and microbiological quality at clients' premises	Site



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DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
MEDICAL DEVICES	<u>Microbiological Tests</u>	Documented In-house Methods	
	Bioburden (pre-sterilisation)	INS 8.4 based on the requirements of BS EN ISO 11737-1:2018 Amd 1:2021 using techniques as appropriate to the sample: INS 8.4.1 membrane filtration INS 8.4.2 pour plate INS 8.4.3 spread plate INS 8.4.4 impression plates INS 8.4.5 swabs INS 8.4.6 agar overlay	A
		Product validation recovery efficiency according to procedure INS 8.5	A
	Endotoxin detection	1) INS 8.7.12 based on the requirements of BS ISO 11737-3:2023 / ANSI AAMI ST72:2019, USP chapter <85> and EP 2.6.14 using Endosafe-PTS/MCS cartridge system	A
		2) INS 8.7.12.1 based on the requirements of BS ISO 11737-3:2023 / ANSI AAMI ST72:2019, USP chapter <85> and EP 2.6.14 using Biotek plate reader	A
	Product validation according to procedure INS 8.7.11/8.7.11.1	A	



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
MEDICAL DEVICES (cont'd) (not for routine product release or a test for sterility as defined by BS EN ISO 11737-2:2020)	<u>Microbiological Tests</u> (cont'd)	Documented In-house Methods	
	Test of sterility Test for sterility	INS 8.9 based on the requirements of BS EN ISO 11737-2:2020 using direct immersion and membrane filtration techniques INS 8.9 based on based on the requirements Appendix XVI of British Pharmacopoeia (current edition) Product inhibition validation according to procedure INS 8.9.1	A A
WATER (process)	Endotoxin detection	1) INS 8.7.9 based on the requirements of BS ISO 11737-3:2023 / ANSI AAMI ST72:2019, USP chapter <85> and EP 2.6.14 using Endosafe-PTS/MCS cartridge system 2) INS 8.7.9.1 based on the requirements of BS ISO 11737-3:2023 / ANSI AAMI ST72:2019, USP chapter <85> and EP 2.6.14 using Biotek plate reader	A A



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ENVIRONMENTAL SAMPLES	<u>Microbiological Tests</u> (cont'd)		
	Incubation and Enumeration of: Contact Plates Settle Plates Active Air Sampling Plates	INS 8.7.2 (settle plates), 8.7.3 (active air sampling), 8.7.4 (contact plates)	A
	Sampling for Contact Plates, Settle Plates, Active Air Sampling Plates	INS 8.7.2 (settle plates), 8.7.3 (active air sampling), 8.7.4 (contact plates) based on the requirements of BS EN 17141:2020	Site
	<u>Physical Tests</u>		
	Airborne Particle Concentration	INS 8.7.1 for the monitoring and classification of air cleanliness based on the requirements of BS EN ISO 14644-1:2015 and BS EN ISO 14644-2:2015	Site
END			