


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <b>21371</b>  Accredited to <b>ISO/IEC 17025:2017</b>	<b>Swann-Morton (Microbiological Laboratory Services) Limited</b>	
	Issue No: 005 Issue date: 26 February 2025	
<b>Penn Works</b> <b>Owlerton Green</b> <b>Sheffield</b> <b>South Yorkshire</b> <b>S6 2BJ</b>	<b>Contact: Darren Hall</b> <b>Tel: +44 (0)114 234 4231</b> <b>E-Mail: darrenhall@swann-morton.com</b> <b>Website: www.swann-morton.com/pages/swannmorton_micro.php</b>	
<b>Testing performed by the Organisation at the locations specified below</b>		

### Locations covered by the organisation and their relevant activities

#### Laboratory locations:

Location details		Activity	Location code
<b>Address</b> Penn Works Owlerton Green Sheffield South Yorkshire S6 2BJ	<b>Local contact</b> Mr Darren Hall	<b>Testing:</b> 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-processig 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
	3) INS 8.7.12.2 using Biotek plate reader and Charles River Trillium recombinant cascade reagent (rCR)	A	
	Product validation according to procedure INS 8.7.11/8.7.11.1 / 8.7.11.2	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	INS 8.9 based on the requirements of BS EN ISO 11737-2:2020 using direct immersion and membrane filtration techniques	A
	Test for sterility	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
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	A
		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
		3) INS 8.7.9.2 using Biotek plate reader and Charles River Trillium recombinant cascade reagent (rCR)	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			