


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: 005 Issue date: 26 February 2025	
	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-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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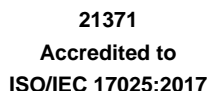
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Testing performed at main address only

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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measured/Range of measurement

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Equipment/Techniques used

Location
codeMEDICAL DEVICES
(cont'd)

Microbiological Tests (cont'd)

Documented In-house Methods

(not for routine product release or a test for sterility as defined by BS EN ISO 11737-2:2020)

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)

A

Product inhibition validation according to procedure INS 8.9.1

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

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3) INS 8.7.9.2 using Biotek plate reader and Charles River Trillium recombinant cascade reagent (rCR)

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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			