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:** 002 **Issue date:** 22 February 2022	
	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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	Swann Morton (Microbiological Laboratory Services) Limited **Issue No:** 002 **Issue date:** 22 February 2022
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	Microbiological Tests	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 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 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
	Sterility	INS 8.9 based on the requirements of BS EN ISO 11737-2:2020 using direct immersion and membrane filtration techniques	A
		Product inhibition validation according to procedure INS 8.9.1	A

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location code
WATER (process)	Microbiological Tests (cont'd)	Documented In-house Methods	
	Endotoxin detection	1) INS 8.7.9 based on the requirements of 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 ANSI AAMI ST72:2019, USP chapter <85> and EP 2.6.14 using Biotek plate reader	A
ENVIRONMENTAL SAMPLES	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 ISO 14698-1:2003	Site
	Physical Tests		
	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