Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

4147

Accredited to ISO/IEC 17025:2017

Andersen Caledonia Ltd

Issue No: 040 **Issue date:** 03 October 2025

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Testing performed by the Organisation at the locations specified

Locations covered by the organisation and their relevant activities

Location details		Activity	Location code
Bellshill Phoenix Crescent Strathclyde Business Park Bellshill ML4 3NJ	**Local contact** Claire Walsh 01698 844 476	**Testing Activities:** Water testing, Environmental testing and Medical Device testing	A
Dunston Barn 7, Office 1B Dunston Business Village Stafford Road Dunston ST18 9FJ	**Local contact** Ronan Stapleton 01785 550420	**Testing Activities:** Water testing, Environmental testing	B
Customer Premises Clean Rooms and other associated controlled environments		**Testing Activities:** Active Air Monitoring	C
Belfast 10 Heron Road, Unit 3B Belfast BT3 9LE	**Local contact** Jenny McDowell	**Testing Activities:** Water testing, Environmental testing and Medical Device testing	D

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
WATERS (non-regulatory)	Microbiological Tests Enumeration of:	Documented In-house Methods	
Drinking water, domestic waters,	Total Aerobic Colony Count	Method No 4173 using pour plate on YEA at 22 °C 68 ± 4 h and 37 °C 44 ± 4h based on MDW, Part 7, 2020	A
Drinking water, Domestic water, Recreational waters (man-made)	Total Aerobic Colony Count	Method No 4173 using spread plate onto YEA at 22 °C for 68 ± 4h and 37 °C for 44 ± 4h based on MDW Part 7, 2020	A
Drinking water, Recreational waters (man-made)	Total Aerobic Colony Count	Method No 4173 using spread plate onto YEA at 22 °C for 68 ± 4h and 37 °C for 44 ± 4h based on MDW Part 7, 2020	B
Drinking water, domestic waters, Recreational waters (man-made)	Coliform (confirmed)	Method No 4216 based on MDW, Part 4b, (2016) using membrane filtration onto MLGA at 30 °C for 4 ± 0.25h then 37 °C for minimum 14h	A
Drinking water, Recreational waters (man-made)	Coliform (confirmed)	Method No 4216 based on MDW, Part 4b, (2016) using membrane filtration onto MLGA at 30 °C for 4 ± 0.25h then 37 °C for minimum 14h	B
Drinking water, domestic waters, Recreational waters (man-made)	*Escherichia coli* (confirmed)	Method No 4216 based on MDW, Part 4b, (2016) using membrane filtration onto MLGA at 30 °C for 4 ± 0.25h then 37 °C for minimum 14h	A
Drinking water, Recreational waters (man-made)	*Escherichia coli* (confirmed)	Method No 4216 based on MDW, Part 4b, (2016) using membrane filtration onto MLGA at 30 °C for 4 ± 0.25h then 37 °C for minimum 14h	B
Drinking water, hospital washer disinfectors, Recreational waters (man-made)	*Pseudomonas aeruginosa* (confirmed)	Method No 4213 based on MDW, Part 8, 2015 using CN plates onto membrane filtration at 37 °C for 44 ± 4h	A

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
WATERS (cont'd)	Microbiological Tests (cont'd) Enumeration of: (cont'd)	Documented In-house Methods	
Drinking water, Recreational waters (man-made)	*Pseudomonas aeruginosa* (confirmed)	Method No 4213 based on MDW, Part 8, 2015 using CN plates and membrane filtration at 37 °C for 44 ± 4h	B
AER Final Rinse Water	Total Viable Count of Water	Method No 4301 using R2A medium by Membrane Filtration based on HTM 01-06 Part E	A
Rinse water (hospital washer disinfectors)	Total Aerobic Colony Count	In-House Method No 4114 by membrane filtration and TSA at 35 °C/3 days based on HTM 2030 (withdrawn)	A
Drinking water, domestic waters, Recreational waters (man-made)	Total Aerobic Colony Count	In-House Method No 4173 using YEA, pour plate, 37 °C for 24h	A
AER waters	Total Aerobic Colony Count	Method 4301 based on HTM01-06 Part E, WHTM 01-06 Part E & BS EN ISO 15883-4 using R2A and membrane filtration at 30 °C for 5 days	B
Reverse Osmosis waters	Total Aerobic Colony Count	Method 4380 based on HTM01-01 Part D using TSA and membrane filtration at 37 °C for 2 days and 22 °C for 3 days	B
Endoscope Washer Disinfector (EWD/AER) waters and Reverse Osmosis waters	Total Aerobic Colony Count	Method 4301 based on NI/HTM01-06 Part E, HTM 0106 Part E, WHTM 01-06 Part E, SHTM 01-06 Part E & BS EN ISO 15883-4 using R2A and membrane filtration at 30 °C for 5 days	D
Endoscope Washer Disinfector (EWD/AER) waters and Reverse Osmosis waters	*Pseudomonas aeruginosa* (confirmed)	Method 4213 based on BS EN ISO 15883-4, NI/HTM 01-06, HTM 01-06, SHTM 01-06, WHTM 01-06. Membrane filtration. CN plates 37°C for 44 ± 4h	D

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
WATERS (cont'd)	Microbiological Tests (cont'd) Enumeration of: (cont'd)	Documented In-house Methods	
Endoscope Washer Disinfector (EWD/AER) waters and Reverse Osmosis waters	Environmental Mycobacteria	Method 4229 using membrane filtration onto supplemented Middlebrook 7H10 Agar at 30 °C and Ziehl Neelsen Stain confirmation, based BS EN ISO 15883- 4:2024, Annex E3, HTM 01-06 Part E, WHTM 01-06 Part ,NI/HTM 0106 part E and SHTM 0106 part E	D
Washer Disinfector, Final Rinse Waters (fed by reverse osmosis supply), Reverse Osmosis water, AER Final Rinse Water	Environmental Mycobacteria	Method 4229 using membrane filtration onto supplemented Middlebrook 7H10 Agar at 30 °C and Ziehl Neelsen Stain confirmation, based BS EN ISO 15883-4:2018, Annex E3, HTM 01-06 Part E, WHTM 01-06 Part E and HTM 2030 (withdrawn)	A, B
Medical Devices Instruments and Bowls	Bioburden Testing	Method 4141 using agitation Extraction in diluent with membrane filtration on to TSA at 35 °C for 3 days for Bacteria and Endospores, SDA at 22 °C for 5 days for Fungi. Based on BS EN ISO ISO 11737-1:2018	A
Inoculated Surrogate Devices – Washer Disinfectors	Recovery & Enumeration of inoculated surrogates - *P. aeruginosa*, *S. aureus*, *B. subtillis* & *C. albicans*	Method 4312 based on BS EN ISO 15883-4 :2018, HTM 01-06 Parts D & E, WHTM 01-06 Parts D & E - using CN plates at at 37 °C for 48h (*P. aeruginosa*), BP plates at 37 °C for 48h (*S. aureus*), TSA plates at 37 °C for 24h (*B. subtillis*) & SDA plates at 37 °C for 5 days (*C. albicans*)	A, B
Inoculated Surrogate Devices – Washer Disinfectors and Sterile Surrogate Devices – Endoscope Storage Cabinet & Endoscope Drying Cabinet	Recovery & Enumeration of inoculated surrogates – *P. aeruginosa*, *S. aureus*, *M. terrae* & *C. albicans* and recovery and enumeration (TVC) of Sterile Surrogate Devices	Method 4312 based on BS EN ISO 15883-4 :2024, HTM 01-06 Parts D & E, NI/HTM 01-06 Parts D & E - using CN plates at 37 °C for 48h (*P. aeruginosa*), BP plates at 37 °C for 48h (*S. aureus*), 7H10 plates at 30 °C for 28 days (*M. terrae*) & SDA plates at 37 °C for 5 days (*C. albicans*)	D

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
WATERS (cont'd)	Microbiological Tests (cont'd)	Documented In-house Methods	
	Enumeration of: (cont'd)		
Sterile Surrogate Devices – Endoscope Storage Cabinet & Endoscope Drying Cabinet	Recovery & Enumerations (TVC) of Sterile Surrogate Devices	Method 4312 section 6.2 based on BS EN 16442:2016 and HTM 01-06 Part D using 90mm TSA plates at 30 °C for 3 days & 90mm SDA plates at 30 °C for 5 days	B
Steam condensate, RO, AER and Final Rinse water	Endotoxin	Method 4378 Turbidimetric assay using the Associates of Cape Cod, Pyros Kinetix Flex PKF96 System to meet HTM01-01 Part C and D United States Pharmacopeia <85>	B
Medical Devices	Endotoxin	Method 4081 by Gel Clot based on United States Pharmacopeia <85> and United States Pharmacopeia <161>	A
	Endotoxin	Method 4405 by Kinetic turbidimetric assay based on United States Pharmacopeia <161>	A
Sterile Glass Vials	Endotoxin	Method 4395 by Kinetic turbidimetric assay based on United States Pharmacopeia <85> and BS ISO 21882 :2019 Annex E	A
Waters for the Preparation of Dialysis Fluid and Ultra-Pure Dialysis Water	Total Aerobic Colony Count	Method 4404 based on BS ISO 23500-3:2024 by spread plate or membrane filtration, using R2A agar at 22°C for 7 days	B
	Detection and Enumeration of:		
Hot and Cold Water supply systems, Drinking water, Recreational waters (man-made)	*Legionella* spp. Including identification of: *L. pneumophila* serogroup 1 and *L. pneumophila* serogroup 2-14	Method 4028 based on BS EN ISO 11731:2017 using filtration with washing, identification by latex agglutination using the Oxoid DR 0800M Latex Kit [Matrix A, Procedure 8,9 and 10. Media A and C]	B

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
WATERS (cont'd)	Microbiological Tests (cont'd)	Documented In-house Methods	
	Molecular Detection:		
Reverse Osmosis and Process Waters	Mycobacterium species Target DNA sequence 16S rRNA Gene Sequence	Method No 4384 using Membrane filtration, recovery of Mycobacterium into 2.0ml wash buffer with Extraction / Immunomagnetic Purification by: 1. Manual or 2. Automated Thermo Kingfisher Flex system Detection using Genesig Q16 qPCR Thermocycler and Primer Design Genesig Easy Detection qPCR Assay kit	B
	Chemical and Physical Tests	Documented In-house Methods	
Reverse Osmosis, Clean/Purified water, Drinking water	pH	Method 22009 using Mettler Toledo pH Meter, based on HTM 01-01 Parts C and D	B

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Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
ENVIRONMENTAL SAMPLES	<u>Microbiological Tests</u>	Documented In-house Methods	
	Environmental settle plates	1) Method 4381 based on BS EN 16442:2015 using 90mm TSA plates at 30 °C for 5 days	B
		2) Method 4008 based on BS EN 17141:2020 using 90mm TSA plates at 35 °C for 3 days & 90mm SDA plates at 22 °C for 5 days	A, B
	Environmental settle plates	3) Method 4381 based on BS EN 16442:2015 using 55mm TSA plates at 30 °C for 5 days	B
		4) Method 4010 based on, BS EN 17141:2020 using 55mm TSA plates at 35 °C for 3 days & 55mm SDA plates at 22 °C for 5 days	A, B
	<u>Physical Tests</u>		
Customer Clean Rooms and associated Controlled Environments	Air monitoring of Biological Air Quality	Procedure 4018 based on BS EN 17141:2020, ISO 14644-1:2015 and ISO 14644-2:2015 using ORUM Trio Bas Duo Air Sampler. Plates handled as follows: TSA incubated at 35 °C for 72 hours SDA incubated at 22°C for 120 hours	C
END			