


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

|   |   |   |
|---|---|---|
|  <p>4147</p> <p>Accredited to<br/>ISO/IEC 17025:2017</p> | <h3>Andersen Caledonia Ltd</h3> <p>Issue No: 036    Issue date: 15 August 2024</p>  |   |
|   | <p><b>Caledonian House</b><br/>Phoenix Crescent<br/>Strathclyde Business Park<br/>Bellshill<br/>Lanarkshire<br/>ML4 3NJ</p> | <p><b>Contact: Mrs C Walsh</b><br/>Tel: +44 (0)1698 844476<br/>Fax: +44 (0)1698 844481<br/>E-Mail: <a href="mailto:cwalsh@andersencaledonia.co.uk">cwalsh@andersencaledonia.co.uk</a><br/>Website: <a href="http://www.andersencaledonia.com">www.andersencaledonia.com</a></p> |
| <p>Testing performed by the Organisation at the locations specified</p>   |   |   |

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

| Location details   | Activity   | Location code |
|--|--|---------------|
| <p><b>Bellshill</b><br/>Phoenix Crescent<br/>Strathclyde Business Park<br/>Bellshill<br/>ML4 3NJ</p> <p style="text-align: right;"><b>Local contact</b><br/><br/>Claire Walsh<br/>01698 844 476</p>                  | <p><b>Testing Activities:</b><br/><br/>Water testing, Environmental testing<br/>and Medical Device testing</p> | A             |
| <p><b>Dunston</b><br/>Barn 7, Office 1B<br/>Dunston Business Village<br/>Stafford Road<br/>Dunston<br/>ST18 9FJ</p> <p style="text-align: right;"><b>Local contact</b><br/><br/>Ronan Stapleton<br/>01785 550420</p> | <p><b>Testing Activities:</b><br/><br/>Water testing, Environmental testing</p>                                | B             |
| <p><b>Customer Premises</b><br/>Clean Rooms and other associated<br/>controlled environments</p>   | <p><b>Testing Activities:</b><br/><br/>Active Air Monitoring</p>   | C             |



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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 |
|--|---|--|---------------|
| WATERS   | <u>Microbiological Tests</u>                          | Documented In-house Methods  |               |
| Potable waters, domestic waters,                                   | Enumeration of:<br>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             |
| Potable water, Domestic water, Pool and Spa Water                  | 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             |
| Potable waters   | 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             |
| Potable waters, domestic waters, pools and spa waters              | 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             |
| Potable waters   | 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             |
| Potable waters, domestic waters, pools and spa waters              | <i>Escherichia coli</i> (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             |
| Potable waters   | <i>Escherichia coli</i> (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             |
| Potable waters, hospital washer disinfectors, pools and spa waters | <i>Pseudomonas aeruginosa</i> (confirmed)             | Method No 4213 based on MDW, Part 8, 2015 using CN plates onto membrane filtration at 37 °C for 44 ± 4h                            | A             |



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| WATERS (cont'd)   | <u>Microbiological Tests</u> (cont'd)                                 | Documented In-house Methods   |               |
| Potable waters  | Enumeration of: (cont'd)<br><i>Pseudomonas aeruginosa</i> (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             |
| Potable waters, domestic waters, pool and spa waters  | 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             |
| Washer Disinfectant, 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          |



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| WATERS (cont'd)  | <u>Microbiological Tests</u> (cont'd)   | Documented In-house Methods  |               |
| Medical Devices<br>Instruments and Bowls   | Enumeration of: (cont'd)<br><br>Bioburden Testing   | Method 4141 using agitation<br>Extraction in diluent with membrane<br>filtration on to TSA at 35 °C for 3 days<br>for Bacteria and Endospores, SDA at<br>22 °C for 5 days for Fungi. Based on<br>BS EN ISO ISO 11737-1:2018  | A             |
| Inoculated Surrogate<br>Devices – Washer<br>Disinfectors                               | Recovery & Enumeration of<br>inoculated surrogates - <i>P.<br/>aeruginosa</i> , <i>S. aureus</i> , <i>B.<br/>subtillis</i> & <i>C. albicans</i> | Method 4312 based on BS EN ISO<br>15883-4 :2018, HTM 01-06 Parts D &<br>E, WHTM 01-06 Parts D & E - using<br>CN plates at at 37 °C for 48h ( <i>P.<br/>aeruginosa</i> ), BP plates at 37 °C for<br>48h ( <i>S. aureus</i> ), TSA plates at 37 °C<br>for 24h ( <i>B. subtillis</i> ) & SDA plates at<br>37 °C for 5 days ( <i>C. albicans</i> ) | A, B          |
| Sterile Surrogate Devices –<br>Endoscope Storage Cabinet<br>& Endoscope Drying Cabinet | Recovery & Enumerations<br>(TVC) of Sterile Surrogate<br>Devices  | Method 4312 section 6.2 based on<br>BS EN 16442:2016 and HTM 01-06<br>Part D using 90mm TSA plates at 30<br>°C for 3 days & 90mm SDA plates at<br>30 °C for 5 days   | A, B          |
| Steam condensate, RO,<br>AER and Final Rinse water                                     | Endotoxin   | Method 4378 Turbidimetric assay<br>using the Associates of Cape Cod,<br>Pyros Kinetix Flex PKF96 System to<br>meet HTM01-01 Part C and D United<br>States Pharmacopeia <85>  | B             |
| Medical Devices  | Endotoxin   | Method 4081 by Gel Clot based on<br>United States Pharmacopeia <85><br>and United States Pharmacopeia<br><161>   | A             |
|  | Endotoxin   | Method 4405 by Kinetic turbidimetric<br>assay based on United States<br>Pharmacopeia <161>   | A             |
| Sterile Glass Vials  | Endotoxin   | Method 4395 by Kinetic turbidimetric<br>assay based on United States<br>Pharmacopeia <85> and BS ISO<br>21882 :2019 Annex E  | A             |



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| WATERS (cont'd)   | <u>Microbiological Tests</u> (cont'd)   | Documented In-house Methods   |               |
| Hot and Cold Water supply systems, Potable waters (non-regulatory)    | Detection and Enumeration of:<br><br><i>Legionella</i> spp. including identification of: <i>L. pneumophila</i> serogroup 1 and <i>L. pneumophila</i> 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<br>[Matrix A, Procedure 8,9 and 10. Media A and C]  | B             |
| Reverse Osmosis and Process Waters                                    | <u>Molecular Detection</u><br><br>Mycobacterium species<br>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:<br>1. Manual or<br>2. Automated Thermo Kingfisher Flex system<br><br>Detection using Genesig Q16 qPCR Thermocycler and Primer Design Genesig Easy Detection qPCR Assay kit | B             |
| Reverse Osmosis, Clean/Purified water, potable water (non-regulatory) | <u>Chemical and Physical Tests</u><br><br>pH  | Documented In-house Methods<br><br>Method 22009 using Mettler Toledo pH Meter, based on HTM 01-01 Parts C and D   | B             |
| Reverse Osmosis, Clean/Purified water                                 | Total organic carbon  | Method 22013 using Beckman Coulter TOC Analyser, based on HTM 01-06 Part E  | B             |



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| 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 :<br>TSA incubated at 35 °C for 72 hours<br>SDA incubated at 22°C for 120 hours | C             |
| END   |   |  |               |