**Schedule of Accreditation**

issued by

**United Kingdom Accreditation Service**

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

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### NHS Wales Shared Services Partnership

trading as Surgical Materials Testing Laboratory

**Issue No:** 026  
**Issue date:** 15 February 2019

<table>
<thead>
<tr>
<th>Address</th>
<th>Local contact</th>
<th>Activity</th>
<th>Location code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Princess of Wales Hospital</td>
<td>Mr P Phillips</td>
<td>Surgical Materials &amp; Medical Devices:</td>
<td>A</td>
</tr>
<tr>
<td>Coity Road</td>
<td>Tel: +44 (0)1656 752820</td>
<td>Physical</td>
<td></td>
</tr>
<tr>
<td>Bridgend</td>
<td>Fax: +44 (0)1656 752830</td>
<td>Mechanical</td>
<td></td>
</tr>
<tr>
<td>South Wales</td>
<td>Email: <a href="mailto:info@smtl.co.uk">info@smtl.co.uk</a></td>
<td>Safety</td>
<td></td>
</tr>
<tr>
<td>CF31 1RQ</td>
<td>Website: <a href="http://www.smtl.co.uk/">www.smtl.co.uk/</a></td>
<td>Health and Hygiene</td>
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</tr>
</tbody>
</table>

**Contact:** Mr P Phillips

Tel: +44 (0)1656 752820  
Fax: +44 (0)1656 752830  
E-Mail: info@smtl.co.uk  
Website: www.smtl.co.uk/

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**Testing performed by the Organisation at the locations specified**

**Laboratory locations:**

<table>
<thead>
<tr>
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</tr>
<tr>
<td>Mid Glamorgan</td>
<td>Email: <a href="mailto:info@smtl.co.uk">info@smtl.co.uk</a></td>
<td>Health and Hygiene</td>
</tr>
<tr>
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<td>Website: <a href="http://www.smtl.co.uk/">www.smtl.co.uk/</a></td>
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**Site activities performed away from the locations listed above:**

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<tbody>
<tr>
<td>Controlled Clean Rooms</td>
<td>Mr P Phillips</td>
<td>Classification of Air Cleanliness</td>
<td>S1</td>
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<tr>
<td></td>
<td>Tel: +44 (0)1656 752820</td>
<td>Active Air and Surface</td>
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<tr>
<td></td>
<td>Fax: +44 (0)1656 752830</td>
<td>Microbiological Monitoring</td>
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<tr>
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<td>Email: <a href="mailto:info@smtl.co.uk">info@smtl.co.uk</a></td>
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<tr>
<th>Materials/Products tested</th>
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<tbody>
<tr>
<td><strong>EXTENSIBLE BANDAGES</strong></td>
<td>Physical Testing</td>
<td>Elastic properties (on unwashed samples) TM-393</td>
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<tr>
<td><strong>MEDICAL SPECIMEN CONTAINERS FOR MICROBIOLOGY</strong></td>
<td>Safety Testing</td>
<td>BS 5213:1975, App A BS EN 14254:2004 anx D TM-18</td>
<td>A</td>
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<tr>
<td><strong>COMPRESSION HOSIERY</strong></td>
<td>Physical Testing</td>
<td>Measurement of compression profiles</td>
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<td>Graduated Compression Hosiery - Compression, stiffness, durability</td>
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<td></td>
<td></td>
<td>Anti-embolism hosiery - Compression, stiffness, durability</td>
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<td></td>
<td>Support hosiery - Compression, stiffness</td>
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<tr>
<td><strong>MEDICAL DEVICES (GENERAL)</strong></td>
<td>Safety testing</td>
<td>Endotoxin testing by quantitative kinetic turbimetric method</td>
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</tbody>
</table>

Assessment Manager: CA2
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<td>Health and Hygiene</td>
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<td>Estimation of bioburden</td>
<td>BS EN ISO 11737-1:2018 TM-345</td>
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<td><strong>VAGINAL SPECULUMS</strong></td>
<td>Speculum Break Testing</td>
<td>Documented In-House Method TM-334</td>
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<td><strong>MEDICAL GLOVES</strong></td>
<td>Perforations</td>
<td>BS EN 455-1:2000 TM-22</td>
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<td>Force at Break</td>
<td>BS EN 455-2:2015 TM-342</td>
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<td>Extractable Protein</td>
<td>BS EN 455-3:2015 Annx A TM-230</td>
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<td>Determination of Removable Surface Powder</td>
<td>BS EN 455-3:2015 Section 5.2 TM-391</td>
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<td>Endotoxins</td>
<td>BS EN 455-3:2015 Section 5.1 European Pharmacopoeia TM-254</td>
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<td>Dimensions</td>
<td>BS EN 455-2: 2015 TM-343</td>
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<td>BS EN 455-2: 2015 &amp; BS EN 455-3:2015 TM-392</td>
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<td>WOUND DRESSINGS</td>
<td>Physical Testing</td>
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<td>Adhesiveness</td>
<td>BP 1993, Vol 2, App XX H, Test 1</td>
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<td>BP 1993, Addendum 1996, App XX H, Test 1</td>
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<td>TM-186</td>
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<td>BP 1993, Vol 2, App XX H, Test 2</td>
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<td>TM-175</td>
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<td>Dispersion characteristics</td>
<td>BS EN 13726-1:2002, Section 3.6</td>
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<td>BP 1993 Addendum 1995 Alginate Dressing/Packing</td>
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<td>TM-112</td>
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<td>Dispersion/solubility of hydrogel dressings</td>
<td>BS EN 13726-1:2002, Section 3.7</td>
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<td>Free swell absorptive capacity</td>
<td>BS EN 13726-1:2002, Section 3.2</td>
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<td>BP 1993 Addendum 1995 Alginate Dressing/Packing</td>
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<td>BS EN 13726-1:2002, Section 3.3</td>
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<td>BP 1993 Addendum 1996 Semi-permeable hydrocolloid</td>
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<td>Absorbency and fluid retention</td>
<td>Documented In-House Method</td>
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<td>Absorbency under compression</td>
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<td>WOUND DRESSINGS (cont’d)</td>
<td><strong>Physical Testing (cont’d)</strong></td>
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<td>Fluid affinity of amorphous hydrogels</td>
<td>BS EN 13726-1:2002 Section 3.4 TM-238</td>
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<td>Conformability for primary wound dressings</td>
<td>BS EN 13726-4:2003 TM-396</td>
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<td>Moisture vapour transmission of Permeable Film Dressings</td>
<td>BS EN 13726-2: 2002 TM-394</td>
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<td>Moisture Vapour Transmission Rate from Dressings by Electronic Data Capture Method</td>
<td>Supplemented by Documented In-House Method, TM-8, based on BS EN 13726-2:2002</td>
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<td>BP 1993, Addendum 1996-App XX K TM-185</td>
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<td>Test for Bacterial Penetration of Film Dressings</td>
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<td>Test for Bacterial Penetration of Film Dressings</td>
<td>Documented In-House Method TM-43</td>
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<tr>
<td>URETHRAL CATHETERS</td>
<td>Health and Hygiene</td>
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<td>Surface finish</td>
<td>BS EN 1616:1997 Section 4.2 TM-309</td>
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<td>Dimensions</td>
<td>BS EN 1616:1997 Section 4.3 TM-300</td>
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<td>Strength</td>
<td>BS EN 1616:1997 Section 4.4 TM-301</td>
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<td>Connector security</td>
<td>BS EN 1616:1997 Section 4.5 TM-302</td>
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<td>Occlusion of drainage eyes and leakage from balloons</td>
<td>BS EN 1616:1997 Section 4.6.1 TM-303</td>
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<td>Balloon recovery volume</td>
<td>BS EN 1616:1997 Section 4.6.2 TM-304</td>
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<td>URETHRAL CATHETERS</td>
<td>Flow rate</td>
<td>BS EN 1616:1997 Section 4.8 TM-305</td>
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<td>Symbols and labelling</td>
<td>BS EN 1616:1997 Section 4.3.1, 5a &amp; 5b TM-308</td>
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<tr>
<td>URINE COLLECTION BAGS</td>
<td>Physical, mechanical: Rated and test Volume</td>
<td>BS EN ISO 8669-2:1997: Section 6.2 TM-287</td>
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<td>URINE COLLECTION BAGS</td>
<td>Freedom from leakage without load</td>
<td>BS EN ISO 8669-2:1997: Section 6.3 TM-288</td>
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<td>URINE COLLECTION BAGS</td>
<td>Freedom from leakage under load</td>
<td>BS EN ISO 8669-2:1997: Section 6.4 TM-289</td>
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<td>URINE COLLECTION BAGS</td>
<td>Non-return valve</td>
<td>BS EN ISO 8669-2:1997: Section 6.5 TM-290</td>
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<td>URINE COLLECTION BAGS</td>
<td>Strength of attachment systems of bags provided with cutouts</td>
<td>BS EN ISO 8669-2:1997: Section 6.6 TM-291</td>
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<tr>
<td>URINE COLLECTION BAGS</td>
<td>Strength of attachment systems of bags provided with button and buttonhole systems</td>
<td>BS EN ISO 8669-2:1997: Section 6.7 TM-292</td>
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<tr>
<td>URINE COLLECTION BAGS</td>
<td>Strength of integral suspensory systems</td>
<td>BS EN ISO 8669-2:1997: Section 6.8 TM-293</td>
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<td>URINE COLLECTION BAGS</td>
<td>Strength of attachment of the inlet tubing</td>
<td>BS EN ISO 8669-2:1997: Section 6.9 TM-294</td>
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<td>URINE COLLECTION BAGS</td>
<td>Pressure/time required to initiate flow into the bags and filling rate</td>
<td>BS EN ISO 8669-2:1997: Section 6.10 TM-295</td>
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</table>
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<tr>
<td>CONTROLLED CLEAN ROOMS</td>
<td>Physical Testing</td>
<td>BS EN ISO 14644-1:2015 and current GMP guidance TM-266</td>
<td>S1</td>
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<td>Classification of air cleanliness</td>
<td>Documented In-House Method, TM-354, based on current GMP guidance</td>
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<td></td>
<td>Health and Hygiene</td>
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<tr>
<td></td>
<td>Active air and surface microbiological monitoring</td>
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<tr>
<td>FLUIDS</td>
<td>Total Viable Count of Fluid Samples (potable and process water, aqueous solutions and liquids or powders reconstituted in water or aqueous diluents only)</td>
<td>Documented In-House Method, TM-372</td>
<td>A</td>
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