


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

| | | |
|---|--|---|
|  <p>Accredited to ISO/IEC 17025:2005</p> | Abertawe Bro Morgannwg University Local Health Board trading as Surgical Materials Testing Laboratory | |
| | Issue No: 023 | Issue date: 18 January 2017 |
| | Princess of Wales Hospital Coity Road Bridgend Mid Glamorgan CF31 1RQ | Contact: Mr P Philips Tel: +44 (0)1656 652166752820 Fax: +44 (0)1656 667291752830 E-Mail: info@smtl.co.uk Website: www.smtl.co.uk/ |
| Testing performed by the Organisation at the locations specified | | |

Locations covered by the organisation and their relevant activities

Laboratory locations:

| Location details | | Activity | Location code |
|---|--|--|---------------|
| Address Princess of Wales Hospital Coity Road Bridgend Mid Glamorgan CF31 1RQ | Local contact Mr P Philips Tel: +44 (0)1656 752820 Fax: +44 (0)1656 752830 Email: info@smtl.co.uk Website: www.smtl.co.uk/ | <u>Surgical Materials & Medical Devices:</u> Physical Mechanical Safety Health and Hygiene | A |

Site activities performed away from the locations listed above:

| Location details | | Activity | Location code |
|------------------------|--|---|---------------|
| Controlled Clean Rooms | Local contact Mr P Philips Tel: +44 (0)1656 752820 Fax: +44 (0)1656 752830 Email: info@smtl.co.uk Website: www.smtl.co.uk/ | Classification of Air Cleanliness Active Air and Surface Microbiological Monitoring | S1 |



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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 |
|--|--|--|---------------|
| EXTENSIBLE BANDAGES | <u>Physical Testing</u> Elastic properties | BS 7505:1995 (on unwashed samples) TM-393 | A |
| MEDICAL SPECIMEN CONTAINERS FOR MICROBIOLOGY | <u>Safety Testing</u> Leak testing | BS 5213:1975, App A TM-18 | A |
| COMPRESSION HOSIERY | <u>Physical Testing</u> Measurement of compression profiles | Documented In-House Method, TM-71, based on BS 6612:1985(1997) & BS 7672:1993 App A4.2-A4.5 and A4.6 | A |
| | Graduated Compression Hosiery - Compression, stiffness, durability | BS 6612:1985 (2013) excluding section 5 TM-225 | A |
| | Anti-embolism hosiery - Compression, stiffness, durability | BS 7672:1993 excluding section 7 excluding section 7 TM-241 | A |
| | Support hosiery - Compression, stiffness | BS 7563:1999 excluding section 6 TM-405 | A |



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| MEDICAL DEVICES (GENERAL) | <u>Safety testing</u> | | |
| | Endotoxin testing by quantitative kinetic turbidimetric method | British & European Pharmacopoeia Bacterial Endotoxin Test USP Transfusion and Infusion Assemblies and Similar Medical Devices TM-254 | A |
| VAGINAL SPECULUMS | <u>Health and Hygiene</u> | | |
| | Estimation of bioburden | BS EN ISO 11737-1:2006 TM-345 | A |
| MEDICAL GLOVES | Speculum Break Testing | Documented In-House Method TM-334 | A |
| | <u>Health and Hygiene</u> | | |
| | Perforations Force at Break | BS EN 455-1:2000 TM-22 BS EN 455-2:2015 TM-342 | A A |
| | Extractable Protein | BS EN 455-3:2015 Annex A TM-230 | A |
| | Determination of Removable Surface Powder | BS EN 455-3:2015 Section 5.2 BS EN ISO 21171:2006 TM-391 | A A |
| | Endotoxins | BS EN 455-3:2006 Section 5.1 European Pharmacopoeia TM-254 | A A |
| | Dimensions | BS EN 455-2: 2015 TM-343 | A |



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| MEDICAL GLOVES (cont'd) | <u>Health and Hygiene</u> | | |
| | Labelling | BS EN 455-2: 2015 & BS EN 455-3:2015 TM-392 | A |
| WOUND DRESSINGS | <u>Physical Testing</u> | | |
| | Adhesiveness | BP 1993, Vol 2, App XX H, Test 1 BP 1993, Addendum 1996, App XX H, Test 1 TM-186 | A A |
| | Dispersion characteristics | BS EN 13726-1:2002 Section 3.6 BP 1993 Addendum 1995 Alginate Dressing/Packing TM-112 | A A |
| | Dispersion/solubility of hydrogel dressings | BS EN 13726-1:2002 Section 3.7 TM-116 | A |
| | Free swell absorptive capacity | BS EN 13726-1:2002 Section 3.2 BP 1993 Addendum 1995 Alginate Dressing/Packing – Absorbency TM-101 | A A |
| | Fluid handling capacity | BS EN 13726-1:2002 Section 3.3 TM-390 BP 1993 Addendum 1996 - Semi-permeable hydrocolloid dressings - Fluid Handling TM-65 | A A |



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| WOUND DRESSINGS (cont'd) | <u>Physical Testing</u> | | |
| | Fluid affinity of amorphous hydrogels | BS EN 13726-1:2002 Section 3.4 TM-238 | A |
| | Conformability for primary wound dressings | BS EN 13726-4:2003 TM-396 | A |
| | Moisture vapour transmission of Permeable Film Dressings | BS EN 13726-2: 2002 TM-394 | |
| | Moisture Vapour Transmission Rate from Dressings by Electronic Data Capture Method | Supplemented by Documented In-House Method, TM-8, based on BS EN 13726-2:2002 | A |
| | Waterproofness | BS EN 13726-3: 2003 TM-395 BP 1993, Vol 2, App XX K TM-185 BP 1993, Addendum 1996 - App XX K | A A A |
| | <u>Biological</u> | | |
| | Test for Bacterial Penetration of Film Dressings | Documented In-House Method TM-43 | A |



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| URETHRAL CATHETERS | <u>Health and Hygiene</u> | | |
| | Surface finish | BS EN 1616:1997 Section 4.2 TM-309 | A |
| | Dimensions | BS EN 1616:1997 Section 4.3 TM-300 | A |
| | Strength | BS EN 1616:1997 Section 4.4 TM-301 | A |
| | Connector security | BS EN 1616:1997 Section 4.5 TM-302 | A |
| | Occlusion of drainage eyes and leakage from balloons | BS EN 1616:1997 Section 4.6.1 TM-303 | A |
| | Balloon recovery volume | BS EN 1616:1997 Section 4.6.2 TM-304 | A |
| | Flow rate | BS EN 1616:1997 Section 4.8 TM-305 | A |
| | Symbols and labelling | BS EN 1616:1997 Section 4.8 4.3.1, 5a & 5b TM-308 | A |
| URINE COLLECTION BAGS | <u>Health and Hygiene</u> | | |
| | Physical, mechanical: Rated and test Volume | BS EN ISO 8669-2:1997: Section 6.1 TM-286 & TM-297 | A |
| | Freedom from leakage without load | Section 6.2 TM-287 | A |



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| URINE COLLECTION BAGS | <u>Health and Hygiene</u> | | |
| | Freedom from leakage under load | Section 6.3 TM-288 | A |
| | Freedom from leakage under impact | Section 6.4 TM-289 | A |
| | Non-return valve | Section 6.5 TM-290 | A |
| | Strength of attachment systems of bags provided with cutouts | Section 6.6 TM-291 | A |
| | Strength of attachment systems of bags provided with button and buttonhole systems | Section 6.7 TM-292 | A |
| | Strength of integral suspensory systems | Section 6.8 TM-293 | A |
| | Strength of attachment of the inlet tubing | Section 6.9 TM-294 | A |
| CONTROLLED CLEAN ROOMS | Pressure/time required to initiate flow into the bags and filling rate | Section 6.10 TM-295 | A |
| | Dimensions | Annex A TM-296 | A |
| | <u>Physical Testing</u> | | |
| | Classification of air cleanliness | BS EN ISO 14644-1:2015 and current GMP guidance TM-266 | S1 |
| | <u>Health and Hygiene</u> | | |
| | Active air and surface microbiological monitoring | Documented In-House Method, TM-354, based on current GMP guidance | S1 |



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| FLUIDS | Total Viable Count of Fluid Samples (potable and process water, aqueous solutions and liquids or powders reconstituted in water or aqueous diluents only). | Documented In-House Method, TM-372 | A |
| END | | | |