


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <b>1492</b> <b>Accredited to</b> <b>ISO/IEC 17025:2017</b>	<b>NHS Wales Shared Services Partnership</b> <b>trading as Surgical Materials Testing Laboratory</b>  <b>Issue No: 034    Issue date: 11 October 2024</b>	
	<b>Princess of Wales Hospital</b> <b>Coity Road</b> <b>Bridgend</b> <b>South Wales</b> <b>CF31 1RQ</b>	<b>Contact: Dr G Hughes</b> <b>Tel: +44 (0)1656 752820</b> <b>Fax: +44 (0)1656 752830</b> <b>E-Mail: info@smtl.co.uk</b> <b>Website: www.smtl.co.uk/</b>
<b>Testing performed by the Organisation at the locations specified</b>		

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

#### Laboratory locations:

Location details	Activity	Location code
<b>Address</b> Princess of Wales Hospital Coity Road Bridgend Mid Glamorgan CF31 1RQ  <b>Local contact</b> Dr G Hughes Tel: +44 (0)1656 752820 Fax: +44 (0)1656 752830 Email: info@smtl.co.uk Website: www.smtl.co.uk/	<u>Surgical Materials &amp; Medical Devices:</u> Physical Mechanical Safety Health and Hygiene	B
<b>Address</b> IP5 Imperial Park Celtic Way Newport NP10 8BE  <b>Local contact</b> Dr G Hughes Tel: +44 (0)1656 752820 Fax: +44 (0)1656 752830 Email: info@smtl.co.uk Website: www.smtl.co.uk	<u>Surgical Materials &amp; Medical Devices:</u> Physical Health and Hygiene	N

#### Site activities performed away from the locations listed above:

Location details	Activity	Location code
Controlled Clean Rooms  <b>Local contact</b> Dr G Hughes 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	B, N
MEDICAL SPECIMEN CONTAINERS FOR MICROBIOLOGY	<u>Safety Testing</u>  Leak testing	BS EN ISO 6717:2021 Annex C TM-18	B
COMPRESSION HOSIERY	<u>Physical Testing</u>  Graduated Compression Hosiery, Anti-Embolism Hosiery and Graduated Support Hosiery – Compression, durability and stiffness	BS 661210:2018 +a1:2022  TM-487	B, N
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 including RO water	B
Samples types including Gowns	<u>Health and Hygiene</u>  Estimation of bioburden	BS EN ISO 11737-1:2018 TM-345	B , N
VAGINAL SPECULUMS	Speculum Break Testing	Documented In-House Method TM-334	B



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
MEDICAL GLOVES	<u>Biological Testing</u>		
	Extractable Protein	BS EN 455-3:2023 Annx A TM-230	B
	Determination of Removable Surface Powder	BS EN 455-3:2023 Section 5.2	B
		BS EN ISO 21171:2006 TM-391	B
	Endotoxins	BS EN 455-3:2023 Section 5.1	B
		European Pharmacopoeia TM-254	B
	<u>Physical Testing</u>		
	Dimensions	BS EN 455-2: 2024 TM-343	B, N
	Labelling	BS EN 455-2: 2024 & BS EN 455-3:2023 TM-392	B, N
	Perforations	BS EN 455-1:2020 +A1 :2022 TM-22	B, N
	Force at Break	BS EN 455-2:2024 TM-342	B, N



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
WOUND DRESSINGS	<u>Physical Testing</u>		
	Free swell absorptive capacity	BS EN 13726:2023 Annex B TM-507	B
	Fluid retention capacity	BS EN 13726:2023 Annex C TM-507	B
	Absorption under compression	BS EN 13726:2023 Annex D TM-508	B
	Fluid Handling Capacity	BS EN 13726:2023 Annex E & N TM-509	B
	Fluid donation of amorphous hydrogel dressings	BS EN 13726:2023 Annex F TM-510	B
	Dispersion characteristics of gelling dressings	BS EN 13726:2023 Annex G TM-511	B
	Moisture vapour transmission rate of a wound dressing when in contact with vapour	BS EN 13726:2023 Annex H TM-512	B
	Moisture vapour transmission rate of a wound dressing when in contact with liquid	BS EN 13726:2023 Annex I TM-512	B
	Waterproofness	BS EN 13726:2023 Annex J TM-513	B, N
	Extensibility and permanent set	BS EN 13726:2023 Annex K TM-514	B



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
WOUND DRESSINGS (cont'd)	<u>Physical Testing</u> (cont'd)		
	Air Expulsion for Fluid Handling Capacity Testing	BS EN 13726:2023 Annex O TM-500	B
	Adhesiveness	BP 1993, Vol 2, App XX H, Test 1	B
		BP 1993, Addendum 1996, App XX H, Test 1 TM-186	B
		BP 1993, Vol 2, App XX H, Test 2 TM-175	B
	Dispersion characteristics	BS EN 13726-1:2002 Section 3.6 TM-112	B
	Dispersion/solubility of hydrogel dressings	BS EN 13726-1:2002 Section 3.7 TM-116	B
	Free swell absorptive capacity	BS EN 13726-1:2002 Section 3.2 TM-101	B
	Fluid handling capacity	BS EN 13726-1:2002 Section 3.3 TM-390	B
	Absorbency and fluid retention	Documented In-House Method TM-404	B
	Absorbency under compression	Documented In-House Method TM-414	B
	Fluid affinity of amorphous hydrogels	BS EN 13726-1:2002 Section 3.4 TM-238	B



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WOUND DRESSINGS (cont'd)	<u>Physical Testing</u> (cont'd)		
	Conformability for primary wound dressings	BS EN 13726-4:2003 TM-396	B
	Moisture vapour transmission of Permeable Film Dressings	BS EN 13726-2: 2002 TM-394	B
	Waterproofness	BS EN 13726-3: 2003 TM-395	B, N
	<u>Biological Testing</u>		
	Test for Bacterial Penetration of Film Dressings	Documented In-House Method TM-43	B , N
URETHRAL CATHETERS	<u>Health and Hygiene</u>		
	Surface finish	BS EN ISO 20696:2018 Section 5.4 TM-309	B
	Dimensions	BS EN ISO 20696:2018 Section 5.5 TM-300	B
	Strength	BS EN ISO 20696:2018 Section 6.1 Annex A TM-301	B
	Connector security	BS EN ISO 20696:2018 Section 6.2 Annex B TM-302	B
	Occlusion of drainage eyes and leakage from balloons	BS EN ISO 20696:2018 Section 6.3 Annex C TM-303	B
	Balloon recovery volume	BS EN ISO 20696:2018 Sections 6.4.2 Annex D TM-304	B



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URETHRAL CATHETERS (cont'd)	<u>Health and Hygiene</u> (cont'd)		
	Flow rate	BS EN ISO 20696:2018 Section 6.5 Annex E TM-305	B
	Symbols and labelling	BS EN ISO 20696:2018 Sections 5.5, 7.2, 7.3 TM-308	B
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	B, N
	Freedom from leakage without load	BS EN ISO 8669-2:1997: Section 6.2 TM-287	B, N
	Freedom from leakage under load	BS EN ISO 8669-2:1997: Section 6.3 TM-288	B, N
	Freedom from leakage under impact	BS EN ISO 8669-2:1997: Section 6.4 TM-289	B, N
	Non-return valve	BS EN ISO 8669-2:1997: Section 6.5 TM-290	B, N
	Strength of attachment systems of bags provided with cutouts	BS EN ISO 8669-2:1997: Section 6.6 TM-291	B, N
	Strength of attachment systems of bags provided with button and buttonhole systems	BS EN ISO 8669-2:1997: Section 6.7 TM-292	B, N
	Strength of integral suspensory systems	BS EN ISO 8669-2:1997: Section 6.8 TM-293	B, N



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URINE COLLECTION BAGS (cont'd)	<u>Health and Hygiene</u> (cont'd)		
	Strength of attachment of the inlet tubing	BS EN ISO 8669-2:1997: Section 6.9 TM-294	B, N
	Pressure/time required to initiate flow into the bags and filling rate	BS EN ISO 8669-2:1997: Section 6.10 TM-295	B, N
	Dimensions	BS EN ISO 8669-2:1997: Annex A TM-296	B, N
Disposable Pulp Products	Water retention tests	PAS 29:1999 TM:491	B, N
	Maceration Test	PAS 29:1999 TM-492	B
CONTROLLED CLEAN ROOMS	<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
FLUIDS	Total Viable Count by filtration or spread plate method 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	B, N
END			