

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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



1492

Accredited to
ISO/IEC 17025:2017

NHS Wales Shared Services Partnership trading as Surgical Materials Testing Laboratory

Issue No: 030

Issue date: 03 March 2021

Princess of Wales Hospital
Coity Road
Bridgend
South Wales
CF31 1RQ

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/

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 Phillips 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 Phillips 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 BS EN 14254:2004 anx D 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	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 TM-241	A
	Support hosiery - Compression, stiffness	BS 7563:1999 excluding section 6 TM-405	A
	Graduated Compression Hosiery, Anti-Embolism Hosiery and Graduated Support Hosiery – Compression, durability and stiffness	BS 661210:2018 TM-487	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 including RO water	A
	<u>Health and Hygiene</u> Estimation of bioburden	BS EN ISO 11737-1:2018 TM-345	A
VAGINAL SPECULUMS	Speculum Break Testing	Documented In-House Method TM-334	A
MEDICAL GLOVES	Perforations Force at Break	BS EN 455-1:2020 TM-22 BS EN 455-2:2015 TM-342	A A
	Extractable Protein	BS EN 455-3:2015 Annx 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 455-3:2015 Section 5.1 European Pharmacopoeia TM-254	A A
	Dimensions	BS EN 455-2: 2015 TM-343	A
	Labelling	BS EN 455-2: 2015 & BS EN 455-3:2015 TM-392	A



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WOUND DRESSINGS	<u>Physical Testing</u>		
	Adhesiveness	BP 1993, Vol 2, App XX H, Test 1	A
		BP 1993, Addendum 1996, App XX H, Test 1	A
		TM-186	
		BP 1993, Vol 2, App XX H, Test 2	A
		TM-175	
	Dispersion characteristics	BS EN 13726-1:2002 Section 3.6	A
		BP 1993 Addendum 1995 Alginate Dressing/Packing	A
		TM-112	
	Dispersion/solubility of hydrogel dressings	BS EN 13726-1:2002 Section 3.7	A
	TM-116		
Free swell absorptive capacity	BS EN 13726-1:2002 Section 3.2	A	
	BP 1993 Addendum 1995 Alginate Dressing/Packing – Absorbency	A	
	TM-101		
Fluid handling capacity	BS EN 13726-1:2002 Section 3.3	A	
	TM-390		
	BP 1993 Addendum 1996 - Semi-permeable hydrocolloid dressings - Fluid Handling	A	
	TM-65		
Absorbency and fluid retention	Documented In-House Method	A	
	TM-404		
Absorbency under compression	Documented In-House Method	A	
	TM-414		



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WOUND DRESSINGS (cont'd)	<u>Physical Testing</u> (cont'd)		
	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	A
	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 BP 1993, Addendum 1996- App XX K TM-185	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 ISO 20696:2018 Section 5.4 TM-309	A
	Dimensions	BS EN ISO 20696:2018 Section 5.5 TM-300	A
	Strength	BS EN ISO 20696:2018 Section 6.1 Annex A TM-301	A
	Connector security	BS EN ISO 20696:2018 Section 6.2 Annex B TM-302	A
	Occlusion of drainage eyes and leakage from balloons	BS EN ISO 20696:2018 Section 6.3 Annex C TM-303	A
Balloon recovery volume	BS EN ISO 20696:2018 Sections 6.4.2 Annex D TM-304	A	
URETHRAL CATHETERS	Flow rate	BS EN ISO 20696:2018 Section 6.5 Annex E TM-305	A
	Symbols and labelling	BS EN ISO 20696:2018 Sections 5.5, 7.2, 7.3 TM-308	A



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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	BS EN ISO 8669-2:1997: Section 6.2 TM-287	A
	Freedom from leakage under load	BS EN ISO 8669-2:1997: Section 6.3 TM-288	A
	Freedom from leakage under impact	BS EN ISO 8669-2:1997: Section 6.4 TM-289	A
	Non-return valve	BS EN ISO 8669-2:1997: Section 6.5 TM-290	A
	Strength of attachment systems of bags provided with cutouts	BS EN ISO 8669-2:1997: Section 6.6 TM-291	A
	Strength of attachment systems of bags provided with button and buttonhole systems	BS EN ISO 8669-2:1997: Section 6.7 TM-292	A
	Strength of integral suspensory systems	BS EN ISO 8669-2:1997: Section 6.8 TM-293	A
URINE COLLECTION BAGS	Strength of attachment of the inlet tubing	BS EN ISO 8669-2:1997: Section 6.9 TM-294	A
	Pressure/time required to initiate flow into the bags and filling rate	BS EN ISO 8669-2:1997: Section 6.10 TM-295	A
	Dimensions	BS EN ISO 8669-2:1997: Annex A TM-296	A



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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	A
END			