

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 17025:2005

NHS Wales Shared Services Partnership trading as Surgical Materials Testing Laboratory

Issue No: 025

Issue date: 23 November 2017

Princess of Wales Hospital
Coity Road
Bridgend
Mid Glamorgan
CF31 1RQ

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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
<p>Address Princess of Wales Hospital Coity Road Bridgend Mid Glamorgan CF31 1RQ</p> <p>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/</p>	<p><u>Surgical Materials & Medical Devices:</u> Physical Mechanical Safety Health and Hygiene</p>	A

Site activities performed away from the locations listed above:

Location details	Activity	Location code
<p>Controlled Clean Rooms</p> <p>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/</p>	<p>Classification of Air Cleanliness Active Air and Surface Microbiological Monitoring</p>	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 BS EN 14254:2004 anx D	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 turbimetric 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	A
			BP 1993, Vol 2, App XX K TM-185	A
BP 1993, Addendum 1996 - App XX K			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			