

issued by

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



**Accredited to
ISO/IEC 17025:2017**

Issue No: 033 **Issue date:** 27 November 2023

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

Contact: Dr G Hughes
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

Laboratory locations:

Location details	Activity	Location code
<p>Address Princess of Wales Hospital Coity Road Bridgend Mid Glamorgan CF31 1RQ</p> <p>Local contact Dr G Hughes 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>	B
<p>Address IP5 Imperial Park Celtic Way Newport NP10 8BE</p> <p>Local contact Dr G Hughes 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 Health and Hygiene</p>	N

Site activities performed away from the locations listed above:

Location details	Activity	Location code
<p>Controlled Clean Rooms</p> <p>Local contact Dr G Hughes 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</p> <p>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	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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MEDICAL GLOVES	<u>Biological Testing</u>		
	Extractable Protein	BS EN 455-3:2015 Annx A TM-230	B
	Determination of Removable Surface Powder	BS EN 455-3:2015 Section 5.2 BS EN ISO 21171:2006 TM-391	B B
	Endotoxins	BS EN 455-3:2015 Section 5.1 European Pharmacopoeia TM-254	B B
	<u>Physical Testing</u>		
	Dimensions	BS EN 455-2: 2015 TM-343	B, N
	Labelling	BS EN 455-2: 2015 & BS EN 455-3:2015 TM-392	B, N
	Perforations	BS EN 455-1:2020 TM-22	B , N
	Force at Break	BS EN 455-2:2015 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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WOUND DRESSINGS (Cont.)	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
	Conformability for primary wound dressings	BS EN 13726-4:2003 TM-396	B



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WOUND DRESSINGS (Cont.)	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</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
	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



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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	B
	Freedom from leakage without load	BS EN ISO 8669-2:1997: Section 6.2 TM-287	B
	Freedom from leakage under load	BS EN ISO 8669-2:1997: Section 6.3 TM-288	B
	Freedom from leakage under impact	BS EN ISO 8669-2:1997: Section 6.4 TM-289	B
	Non-return valve	BS EN ISO 8669-2:1997: Section 6.5 TM-290	B
	Strength of attachment systems of bags provided with cutouts	BS EN ISO 8669-2:1997: Section 6.6 TM-291	B
	Strength of attachment systems of bags provided with button and buttonhole systems	BS EN ISO 8669-2:1997: Section 6.7 TM-292	B
	Strength of integral suspensory systems	BS EN ISO 8669-2:1997: Section 6.8 TM-293	B
	Strength of attachment of the inlet tubing	BS EN ISO 8669-2:1997: Section 6.9 TM-294	B
	Pressure/time required to initiate flow into the bags and filling rate	BS EN ISO 8669-2:1997: Section 6.10 TM-295	B
	Dimensions	BS EN ISO 8669-2:1997: Annex A TM-296	B



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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	B , N
END			