


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>UKAS TESTING</p> <p>9145</p> <p>Accredited to ISO/IEC 17025:2017</p>	<h3>Synergy Health Sterilisation UK Limited</h3> <p>Issue No: 006 Issue date: 03 February 2020</p>	
	<p>South Marston Laboratory Thornhill Road South Marston Swindon SN3 4TA</p>	<p>Contact: Rachel Bradley Tel: +44 (0)1793 898 804 E-Mail: rachel_bradley1@steris.com Website: www.steris-labs.com</p>
<p>Testing performed at the above address only</p>		

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
MEDICAL DEVICES	<p><u>Microbiological Tests</u></p> <p>Bioburden (pre-sterilisation)</p> <p>Endotoxin detection</p> <p>Sterility (aerobic and anaerobic organisms), excluding identification</p>	<p>Documented In-house Methods:</p> <p>Work Instruction 3400 based on the requirements of BS EN ISO 11737-1:2018 using agitation, stomaching, ultrasonication, filtration, fluid pathway, flushing, or pour plate/product overlay as determined by method validation</p> <p>Work Instruction 3478 based on the requirements of ASNI AAMI ST72:2001, USP chapter <85> and EP 2.6.14 using kinetic turbidimetric measurement, incorporating method validation according to Work Instruction 3472</p> <p>1) Work Instruction 3401 based the requirements of BS EN ISO 11737-2:2009 using direct product immersion, elution and/or membrane filtration as determined by method validation and incorporating Work Instruction 3525 for the assessment of Bacteriostatis and Fungistatis properties</p>



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MEDICAL DEVICES (cont'd)	<u>Microbiological Tests</u> (cont'd) Sterility (aerobic and anaerobic organisms), excluding identification (cont'd)	Documented In-house Methods: 2) Work Instruction 4401 based on the requirements of USP chapter 71 using direct product immersion, elution and/or membrane filtration as determined by method validation and incorporating Work Instruction 3525 for the assessment of Bacteriostatis and Fungistatis properties
END		