


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>9145</p> <p>Accredited to ISO/IEC 17025:2017</p>	<h3>Synergy Health Sterilisation UK Limited</h3> <p>Issue No: 012 Issue date: 27 January 2025</p>	
	<p>Unit 125 Faraday Park Faraday Road Dorcan Swindon SN3 5JF</p>	<p>Contact: Panagiota Loule Tel: +44 (0)1793 898 802 E-Mail: Panagiota_Loule@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
<p>MEDICAL DEVICES (Including non-CE marked "medical devices" such as surgical drapes, disinfectants for sterility testing)</p> <p>(not for routine product release or a test for sterility as defined by BS EN ISO 11737-2:2020)</p>	<p><u>Microbiological Tests</u></p> <p>Bioburden (pre-sterilisation)</p> <p>Test of sterility (aerobic organisms), excluding identification</p> <p>Test for sterility (aerobic and anaerobic organisms), excluding identification</p> <p>Endotoxin detection</p>	<p>Documented In-house Methods:</p> <p>Work Instruction Q08-WI-001624 based on the requirements of BS EN ISO 11737-1:2018+A1:2021 using agitation, stomaching, ultrasonication, filtration, or pour plate/product overlay/direct inoculation as determined by method validation</p> <p>1) Work Instruction Q08-WI-001625 based the requirements of BS EN ISO 11737-2:2020 using direct product immersion, elution and/or membrane filtration as determined by method validation and incorporating Work Instruction Q08-WI-001634 for the assessment of Bacteriostatis and Fungistatis properties</p> <p>2) Work Instruction Q08-WI-001625 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 Q08-WI-001634 for the assessment of Bacteriostatis and Fungistatis properties</p> <p>Work Instruction Q08-WI-001631 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 Q08-WI-001630</p>
<p>END</p>		