Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

9145

Accredited to ISO/IEC 17025:2017

Synergy Health Sterilisation UK Limited

Issue No: 013 **Issue date:** 07 February 2025

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Testing performed at the above address only

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
MEDICAL DEVICES (Including non-CE marked "medical devices" such as surgical drapes, disinfectants for sterility tesing)	<u>Microbiological Tests</u> Bioburden (pre-sterilisation)	Documented In-house Methods: 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
(not for routine product release or a test for sterility as defined by BS EN ISO 11737-2:2020)	Test of sterility (aerobic organisms), excluding identification	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
	Test for sterility (aerobic and anaerobic organisms), excluding identification	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
	Endotoxin detection	Work Instruction Q08-WI-001631 based on the requirements of ISO 11737-3:2023, ANSI/AAMI ST72:2019, USP chapter <85> and EP 2.6.14 using kinetic turbidimetric measurement, incorporating method validation according to Work Instruction Q08-WI-001630

END