Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

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Accredited to ISO/IEC 17025:2017

Synergy Health Sterilisation UK Limited

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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	<u>Microbiological Tests</u>	Documented In-house Methods:
	Bioburden (pre-sterilisation)	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
	Endotoxin detection	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
	Sterility (aerobic and anaerobic organisms), excluding identification	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

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
MEDICAL DEVICES (cont'd)	Microbiological Tests (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		