Certificate of Accreditation

UKAS
United Kingdom Accreditation Service

Synergy Health Sterilisation UK Limited

Testing Laboratory No. 9145

Is accredited in accordance with International Standard ISO/IEC 17025:2017 – General Requirements for the competence of testing and calibration laboratories.

This accreditation demonstrates technical competence for a defined scope specified in the schedule to this certificate, and the operation of a management system (refer joint ISO-ILAC-IAF Communiqué dated April 2017). The schedule to this certificate is an essential accreditation document and from time to time may be revised and reissued.

The most recent issue of the schedule of accreditation, which bears the same accreditation number as this certificate, is available from www.ukas.com.

This accreditation is subject to continuing conformity with United Kingdom Accreditation Service requirements.

Matt Gantley, *Chief Executive Officer*
United Kingdom Accreditation Service

Initial Accreditation: 24 January 2017
Certificate Issued: 25 January 2021

ilac-MRA

UKAS
United Kingdom Accreditation Service

Scan QR Code to verify

UKAS is appointed as the sole national accreditation body for the UK by The Accreditation Regulations 2009 (SI No 3155/2009) and operates under a Memorandum of Understanding (MoU) with the Department for Business, Energy and Industrial Strategy (BEIS).

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

UKAS TESTING

9145

Accredited to ISO/IEC 17025:2017

Synergy Health Sterilisation UK Limited

Issue No: 009 **Issue date:** 17 October 2023

South Marston Laboratory
Thornhill Road
South Marston
Swindon
SN3 4TA

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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)	Microbiological Tests Bioburden (pre-sterilisation)	Documented In-house Methods: Work Instruction 3400 based on the requirements of BS EN ISO 11737-1:2018+A1:2021 using agitation, stomaching, ultrasonication, filtration, fluid pathway, flushing, or pour plate/product overlay 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 3401 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 3525 for the assessment of Bacteriostatis and Fungistatis properties
	Test for sterility (aerobic and anaerobic organisms), excluding identification	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

UKAS TESTING 9145 Accredited to ISO/IEC 17025:2017	**Schedule of Accreditation** issued by **United Kingdom Accreditation Service** 2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK **Synergy Health Sterilisation UK Limited** **Issue No:** 009 **Issue date:** 17 October 2023
Testing performed at main address only	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
MEDICAL DEVICES	Microbiological Tests (cont'd) Endotoxin detection	Documented In-house Methods: 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
END		