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of SAMM 309 dated 24 June 2025)

LABORATORY LOCATION/ CENTRAL OFFICE:	Synergy Sterilisation (M) Sdn. Bhd. Plot 203 Kuala Ketil Industrial Estate 09300 Kuala Ketil, Kedah , 9300, KEDAH MALAYSIA
ACCREDITED SINCE :	24 JUNE 2025
FIELD(S) OF TESTING:	CHEMICAL MICROBIOLOGICAL

This laboratory has demonstrated its technical competence to operate in accordance with MS ISO/IEC 17025:2017 (ISO/IEC 17025:2017).

This laboratory's fulfillment of the requirements of ISO/IEC 17025 means the laboratory meets both the technical competence requirements and management system requirements that are necessary for it to consistently deliver technically valid test results and calibrations. The management system requirements in ISO/IEC 17025 are written in language relevant to laboratory operations and operate generally in accordance with the principles of ISO 9001 (see Joint ISO-ILAC-IAF Communiqué dated April 2017).

CENTRAL LOCATION:	Synergy Sterilisation (M) Sdn. Bhd. Plot 203 Kuala Ketil Industrial Estate 09300 Kuala Ketil, Kedah , 9300, Kedah
FIELD(S) OF TESTING :	CHEMICAL, MICROBIOLOGICAL

SCOPE OF TESTING : CHEMICAL

Material / Product Tested	**Type Of Test / Properties Measured / Range Of Measurement**	**Standard Test Methods / Equipment / Techniques**
Medical Devices	1. Ethylene Oxide Sterilization Residues 2. Ethylene Chlorohydrin Sterilization Residues 3. Ethylene Glycol Sterilization Residues	EN ISO 10993-7:2008 / Amd.1:2019 EN ISO 10993-7:2008 + A1: 2022

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SCOPE OF TESTING : MICROBIOLOGICAL

Material / Product Tested	**Type Of Test / Properties Measured / Range Of Measurement**	**Standard Test Methods / Equipment / Techniques**
Medical Devices	Sterility Test	SSSB LWI 52 (Q02-WI-000212) USP 43-2020 <71>
	Test of sterility performed in the validation of a sterilization process	SSSB LWI 51 (Q02-WI-000211) EN ISO 11737-2, 2020
	Determination of a population of microorganism on products (Estimation of Product Bioburden)	SSSB LWI 16 (Q02-WI-000178) ISO 11737-1, 2018
Biological Indicator	Sterility Test	SSSB LWI 15 (Q02-WI-000177) USP 43 - 2020<71>
Sampling Air Borne Microorganism a) Surface Air System Sampler B) Settling Plates	Total Bacteria & Fungal Count Total Bacteria & Fungal Count	SSSB LWI 59 (Q02-WI-000219) (In-house method based on USP 43 - 2020 <1116>)
Surface Sampling A) Contact / Rodac Plate B) Swabs	Total Bacteria & Fungal Count	SSSB LWI 59 (Q02-WI-000219) (In-house method based on USP 43 - 2020 <1116>)
	Total Bacteria & Fungal Count	SSSB LWI 24 (Q02-WI-000184) (In-house method based on USP 43 - 2020 <1116>)
Biological Indicators	Spore count	SSSB LWI 14 (Q02-WI-000176) USP USP 43 - 2020 <55> ISO 11138-1 : 2017 ISO 11138-2 : 2017 ISO 11138-3 : 2017 ISO 11138-4 : 2017
Medical Device Water Liquids	Total Plate Count	SSSB LWI 33 (Q02-WI-000193) In house method based on USP 43 - 2020 <61>, <62>, USPNF 2021 ISSUE 3 <1231>, APHA 9222A, AOAC 991.14
	Presence and Absence of Pathogen	SSSB LWI 33 (Q02-WI-000193) In house method based on USP 43 - 2020 <61>, <62>, USPNF 2021 ISSUE 3 <1231>, APHA 9222A, AOAC 991.14
	Detection and Identification of Pathogen	SSSB LWI 33 (Q02-WI-000193) In house method based on USP 43 - 2020 <61>, <62>, USPNF 2021 ISSUE 3 <1231>, APHA 9222A, AOAC 991.14

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