

NO: SAMM 309

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LABORATORY LOCATION:
(PERMANENT LABORATORY)

SYNERGY STERILISATION (M) SDN. BHD.
(FORMERLY KNOWN AS ISOTRON (M) SDN. BHD.)
PLOT 203, KUALA KETIL INDUSTRIAL ESTATE
09300, KUALA KETIL
KEDAH, MALAYSIA

FIELDS OF TESTING: CHEMICAL & MICROBIOLOGY

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).

SCOPE OF TESTING: CHEMICAL

Materials/ Products 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

Signatory:

1. Noraiza Binti Zakaria

IKM No. M 2794/5535/09

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SCOPE OF TESTING: MICROBIOLOGY

Materials/ Products Tested	Type of Test/ Properties Measured/ Range of Measurement	Standard Test Methods/ Equipment/Techniques
Medical Devices	Sterility Test	USP 43-2020 <71>
	Test of sterility performed in the validation of a sterilization process	EN ISO 11737-2, 2020
	Determination of a population of microorganism on products (Estimation of Product Bioburden)	ISO 11737-1, 2018
Biological Indicator	Sterility Test	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 L WI 59 (In-house method based on USP 43 - 2020 <1116>)
Surface Sampling a) Contact / Rodac Plate b) Swabs	Total Bacteria & Fungal Count Total Bacteria & Fungal Count	SSSB L WI 59 (In-house method based on USP 43 - 2020 <1116>) SSSB L WI 24 (In-house method based on USP 43 - 2020 <1116>)

Note :

USP : United States Pharmacopeia

Signatories:

- | | | |
|----|-----------------------------------|------------------|
| 1. | Jayanthimala Authikesavalu | |
| 2. | Noorani Bt Abd. Samad | MJMM 0496 |
| 3. | Noor Zahidah Bt. Abdullah | MJMM 0497 |

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SCOPE OF TESTING: MICROBIOLOGY

Materials/ Products Tested	Type of Test/ Properties Measured/ Range of Measurement	Standard Test Methods/ Equipment/Techniques
Biological Indicators	Spore count	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 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	
	Detection and Identification of Pathogen	

Note :

USP : United States Pharmacopeia
SSSB : Synergy Sterilisation Sdn. Bhd.**Signatories:**

- | | | |
|----|-----------------------------------|------------------|
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