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of SAMM 519 dated 30 November 2023)

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LABORATORY LOCATION:
(PERMANENT LABORATORY)

SANICHEM RESOURCES SDN. BHD.
NO. 7 & 7A, JALAN TIMUR 6/1A
MERCATO@ENSTEK
71760 BANDAR ENSTEK
NEGERI SEMBILAN
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
Sterilized medical devices	Ethylene oxide sterilization residuals a) Ethylene Oxide b) Ethylene Chlorohydrin c) Ethylene Glycol	In-house Method [TM-001] based on ISO 10993-7 (2008) : Amd.1 (2019)
Aqueous solution	Ethylene Oxide	In-house Method [TM-002] based on ISO 10993-7 (2008) : Amd.1 (2019)
	Ethylene Chlorohydrin	In-house Method [TM-003] based on ISO 10993-7 (2008) : Amd.1 (2019)
	Ethylene Glycol	
Ethylene oxide gas	Relative % purity of gas	In-house Method [TM-005] based on US-EPA Method 8000C: Determinative Chromatographic Separations (2003)

Notes:

ISO – International Organization for Standardization
 US EPA – United States Environmental Protection Agency
 TM – Test Method

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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	In-house Method [TM-500] Sterility Test-Direct Immersion based on ISO 11737-2:2019
		USP 43-NF 38 Microbiological Test: Sterility Test-Direct Inoculation, 2020
	Bioburden	In-house Method [TM-505] based on ISO 11737-1:2018 + USP <61> and USP <62>
	Bacteriostasis and Fungistasis	In-house Method [TM-504] based on ISO 11737-2:2019
		USP 43-NF 38 Microbiological Test / <71> Sterility test, 2019
	Endotoxin (Kinetic Turbidimetric Method)	In-house Method [TM-508] based on USP Chapter <85> Bacterial Endotoxins Test and USP Chapter <161> Transfusion and Infusion Assemblies and Similar Medical Devices, 2012
Biological Indicator	Sterility	In-house Method [TM-501] based on ISO 11138-1:2017
	Population Counts	In-house method [TM-506] based on ETIGAM Technical Data Sheet :2015
		In-house method [TM-507] based on 3M Technical Bulletin-05-000003:2008

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SCOPE OF TESTING: MICROBIOLOGY

Materials/ Products Tested	Type of Test/ Properties Measured/ Range of Measurement	Standard Test Methods/ Equipment/Techniques
Environmental sample: Air (Total plate count, aerobic bacteria and yeast & mold)	Active sampling	In-house method [TM-800] based on ISO 14698-1:2003 and USP<1116>
	Passive sampling	In-house method [TM-801] based on ISO 14698-1:2003 and USP<1116>
Surface (Total plate count, aerobic bacteria and yeast & mold)	Contact plate	In-house method [TM-804] based on ISO 14698-1:2003 and USP<1116>
	Hand Swab	In-house method [TM-802] based on Public Health England. Detection and Enumeration of Bacteria in Swabs and other Environmental Samples. Microbiology Services. Food, Water & Environmental Microbiology Standard Method E1; Version 2.(2014)
	Sponge Swab	In-house method [TM-803] based on ISO 14698-1:2003
Water Water for injection, potable water, distilled water	Endotoxin (Kinetic Turbidimetric Method)	In-house method [TM-508] based on USP Chapter <85> Bacterial Endotoxins Test and USP Chapter <161> Transfusion and Infusion Assemblies and Similar Medical Devices
Bacteria Identification Bacteria and Yeast	Bacteria and Yeast Identification	USP Chapter <1113>, Remel RapID panels and Biomeriux API ID strips (Miniaturized Biochemical Tests)

Notes:

ISO – International Organization for Standardization

USP – United States Pharmacopeia

NF – National Formulary

TM – Test Method