


**NO: SAMM 321**(Issue 2, 03 September 2025 replacement  
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<b>LABORATORY LOCATION/ CENTRAL OFFICE:</b>  	Molnlycke Health Care Sdn. Bhd., Kuala Ketil Plot 204, Kawasan Perindustrian Kuala Ketil 09300 Kuala Ketil, Kedah , 09300, <b>KEDAH</b> <b>MALAYSIA</b>
<b>ACCREDITED SINCE :</b>	03 SEPTEMBER 2025
<b>FIELD(S) OF TESTING:</b>	MECHANICAL 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).

<b>CENTRAL LOCATION:</b>	Molnlycke Health Care Sdn. Bhd., Kuala Ketil Plot 204, Kawasan Perindustrian Kuala Ketil 09300 Kuala Ketil, Kedah , 09300, Kedah
<b>FIELD(S) OF TESTING :</b>	MECHANICAL, MICROBIOLOGICAL

**SCOPE OF TESTING : MECHANICAL**

Material / Product Tested	Type Of Test / Properties Measured / Range Of Measurement	Standard Test Methods / Equipment / Techniques
Natural Rubber And Synthetic Rubber Surgical Gloves/ Examination Gloves	Tensile Properties	ASTM D412-16 (Reapproved 2021) (Test Method A) SS EN 455-2: 2024 SS ISO 37: 2024 (dumb-bell shape only)
	Ageing Test	ASTM D573-04 (Reapproved 2019) ISO 188: 2023 6th Edition  ISO 23529: 2016 Preparing and conditioning Test Pieces for Physical Test Methods

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Material / Product Tested	Type Of Test / Properties Measured / Range Of Measurement	Standard Test Methods / Equipment / Techniques
	Water Tightness Test for Detection of Holes	ASTM D 5151-19 EN (Reapproved 2023) SS EN 455-1: 2020+A2:2024 ISO 10282: 2023 4th Edition  Note: Product tested in accordance to specifications below:  ASTM D3577-19 (Reapproved 2023) ASTM D3578-19 (Reapproved 2023) ISO 10282: 2023 4th Edition

**SCOPE OF TESTING : MICROBIOLOGICAL**

Material / Product Tested	Type Of Test / Properties Measured / Range Of Measurement	Standard Test Methods / Equipment / Techniques
Natural Rubber And Synthetic Rubber Surgical Gloves	Endotoxin Content	In-House Method: Ref. No. SOP LR 7002 Limulus Amebocyte Lysate (LAL) Test by Kinetic Turbidimetric based on ASTM D7102-17 (Reapproved 2022) and SS EN 455-3:2023 and ISO 11737-3:2023  In-House Method: Ref. No. SOP LR 7005 Preparation of Glove Extraction Rinse to Determine Bacteria Endotoxin by LAL Test, based on ASTM D7102-17 (Reapproved 2022) and SS EN 455- 3:2023 and ISO 11737-3:2023
Natural Rubber And Synthetic Rubber Surgical Gloves/ Examination Gloves	Estimation of population of microorganism on products (Estimation of Product Bioburden)	ISO 11737-1:2018/Amd. 1:2021 SS EN ISO 11737-1: 2018
	Sterility Test	In-House Method: Ref. No. SOP 433.59 Microbial Assay: Sterility Test, based on ISO 11737-2:2019, SS EN ISO 11737-2:2020

## Schedule

Issue date: 03 September 2025

Valid Until: -



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