Note: This report is issued subject to the Testing and Certification Regulations of the TÜV SÜD Group and the General Terms and Conditions of Business of TÜV SÜD PSB Pte Ltd. In addition, this report is governed by the terms set out within this report.



Add value. Inspire trust.

SUBJECT

Testing of Gloves

CLIENT

Medtecs (Taiwan) Corp. 11F., No. 9, Songgao Rd., Xinyi Dist., Taipei City, Taiwan

SAMPLE SUBMISSION DATE

20 Nov 2023

TEST DATE

20 Nov 2023 to 29 Nov 2023

DESCRIPTION OF SAMPLES

S/N	Product Description	Brand/ Model	Size	Colour	Lot No.	Manufacturing date	Sample Received (pieces)	Manufacturer
1	"Medtecs" Examination Gloves (Powder-Free) (Non-Sterile)	Medtecs	M	Blue	232461309BL4.5g	2023-09-03	400	RMKH Glove (Cambodia) Co., Ltd.

Lot size as specified by client: 35,001 to 150,000 pieces

METHOD OF TEST

As requested by client, the test was conducted as follows:

ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application

- Clauses 6.1.2 & 7.3 Freedom from Holes (Cross-reference to Test Method D5151)
- Clauses 6.1.4 & 7.5 Physical Requirements Test Die C, accelerated aging conducted according to Clause 7.5.2.1: temperature of 70±2°C for 166±2h (Cross-reference to Test Method D412 and D573)
- Clauses 6.1.5 & 7.6 Powder-free Residue (Cross-reference to Test Method D6124)

Note: Dimensions test was excluded in this report.



Laboratory: TÜV SÜD PSB Pte. Ltd. 15 International Business Park TÜV SÜD @ IBP Singapore 609937 Phone: +65-6778 7777 E-mail: info.sg@tuvsud.com https://www.tuvsud.com/sg Co. Reg: 199002667R Regional Head Office: TÜV SÜD Asia Pacific Pte. Ltd. 15 International Business Park TÜV SÜD @ IBP Singapore 609937

TÜV



RESULTS

Sample: "Medtecs" Examination Gloves, Powder-Free, Non-Sterile, Size M, Blue, Lot no. 232461309BL4.5g

Table 1: Results for Freedom from Holes

Inspection level/ AQL: G-1/2.5

Clause	Tests	Requirements	No. of non- conformances allowed (pieces)	Number tested (pieces)	Actual no. of non- conformances found (pieces)	Inferred results
4 5	Freedom from holes	Shall not leak	10	200	3	Passed

Table 2: Results for Physical Requirements Test - before accelerated aging

Inspection level/ AQL: S-2/4.0

			Results			Number of pieces			
Clause	Tests	Require- ments	Min.	Mean	Max.	Non- conformances allowed	Tested	Actual non- conformances found	Inferred results
6.1.4	Tensile strength (MPa)	≥ 14	21	24	27	17	13	0	Passed
7.5	Ultimate elongation (%)	≥ 500	506	514	525				

Table 3: Results for Physical Requirements Test - after accelerated aging

Inspection level/ AQL: S-2/4.0

		Б .	Results			Number of pieces			
Clause	Tests	Require- ments	Min.	Mean	Max.	Non- conformances allowed	Tested	Actual non- conformances found	Inferred results
6.1.4	Tensile strength (MPa)	≥ 14	19	22	27	1	13	0	Passed
7.5	Ultimate elongation (%)	≥ 400	461	481	507				

Table 4: Results for Powder-Free Gloves

Clause	Tests	Requirements	Number of pieces	Result	Inferred Results
6.1.5 7.6	Powder-free gloves	Powder residue ≤ 2.0 mg	5	0.20 mg per glove	Passed

REMARKS

 The submitted samples comply with the requirements of ASTM D6319 for the tests listed in Method of Test.

Yeo Poh Kwang Test Officer Wong Bee Hui Product Manager Non-Asset Intensive Laboratories Product Service



APPENDIX



Photo: "Medtecs" Examination Gloves, Powder-Free, Non-Sterile, Size M, Blue, Lot no. 232461309BL4.5g

Table 5: Individual Results for for Physical Requirements Test

	Tensile	Strength	Ultimate E	Elongation	
No		Pa)	(%)		
No.	Before	After	Before	After	
	Aging	Aging	Aging	Aging	
1	22	22	506	477	
2	25	26	516	503	
3	27	19	525	466	
4	23	22	516	492	
5	25	20	518	471	
6	21	21	506	475	
7	26	23	518	487	
8	25	21	520	484	
9	21	20	506	461	
10	25	22	509	490	
11	21	21	513	474	
12	24	27	514	507	
13	25	24	521	473	
Min.	21	19	506	461	
Mean	24	22	514	481	
Max.	27	27	525	507	



Please note that this Report is issued under the following terms:

- 1. This report applies to the sample of the specific product/equipment given at the time of its testing/calibration. The results are not used to indicate or imply that they are applicable to other similar items. In addition, such results must not be used to indicate or imply that TÜV SÜD PSB approves, recommends or endorses the manufacturer, supplier or user of such product/equipment, or that TÜV SÜD PSB in any way "guarantees" the later performance of the product/equipment. Unless otherwise stated in this report, no tests were conducted to determine long term effects of using the specific product/equipment.
- 2. The sample/s mentioned in this report is/are submitted/supplied/manufactured by the Client. TÜV SÜD PSB therefore assumes no responsibility for the accuracy of information on the brand name, model number, origin of manufacture, consignment or any information supplied.
- 3. Nothing in this report shall be interpreted to mean that TÜV SÜD PSB has verified or ascertained any endorsement or marks from any other testing authority or bodies that may be found on that sample.
- 4. This report shall not be reproduced wholly or in parts and no reference shall be made by the Client to TÜV SÜD PSB or to the report or results furnished by TÜV SÜD PSB in any advertisements or sales promotion.
- Unless otherwise stated, the tests were carried out in TÜV SÜD PSB Pte Ltd, 15 International Business Park TÜV SÜD @ IBP Singapore 609937.
- 6. The tests carried out by TÜV SÜD PSB and this report are subject to TÜV SÜD PSB's General Terms and Conditions of Business and the Testing and Certification Regulations of the TÜV SÜD Group.

