

Latex surgical gloves powder-free

MANUFACTURER:	TG MEDICAL SDN BHD (Malaysia)	
INDICATION:	<ul style="list-style-type: none"> • Flexible, soft, with non-slip external surface, anatomically shaped, fit perfectly to the hand, providing the user with comfort of work and at the same time provide a protective barrier against microorganisms • Powder free - avoid skin irritation and postoperative complications caused by the powdering agent • Easy putting on thanks to the internal polymer layer • Designed for wide use in surgery 	
FEATURES:	<ul style="list-style-type: none"> • Raw material: natural rubber latex • Colour: natural latex, white and cream • Cuff: beaded • Powder: powder-free • Protein level: 79 µg/g • Coverage: inner layer covered with polymer • AQL: 1,0 • Residues from chemical agents used for production: below the limit of detection, which reduces the risk of type IV allergy and skin irritation • Excellent grip in dry and wet conditions: reliable grip thanks to the micro-texture on the entire surface of the glove • Shape: anatomical • Classification: <ul style="list-style-type: none"> - Class IIa Medical Device in accordance with MDD 93/42/EEC - Personal Protective Equipment Category III according to Directive 89/686/EEC • Standards: in compliance with requirements of ASTM D3577, EN 455, resistant to penetration of viruses in accordance with ASTM F1671, resistant to penetration of chemicals according to EN 374-3, in accordance with EN 420, tested in accordance with EN 388 • Quality Assurance System: Manufacturing process in accordance with US FDA Quality System Regulation (QSR), BS EN ISO 9001 Quality System and EN ISO 13485 • Individual packaging: double-packed gloves - inner paper packaging with glove size marking and distinguishing left and right hands, external packaging - film • Intermediate packaging: 50 pairs in the dispenser (4 dispensers in a carton) • Marking of individual and intermediate 	



	packaging: name of gloves, type, size, production date / series, expiry date, manufacturer's name • Shelf life: 5 years • Method of sterilization: Gamma radiation • Sizes: 6– 9			
SIZE AND REF:	REF	SIZE	INDICATION	INDIVIDUAL PACKAGING
	TG-0260	6	Used to reduce the risk of patient or user infection during surgical procedures in violation of tissue continuity	1 pair (double packed: inner packaging - paper, external packaging – thermoformed film pack)
	TG-0265	6½		
	TG-0270	7		
	TG-0275	7½		
	TG-0280	8		
	TG-0285	8½		
TG-0290	9			
BASED ON:	marketing materials of: TG Medical SDN BHD (Malaysia)			

TECHNICAL DATA SHEET

Latex surgical gloves powder-free

MANUFACTURER:	TG MEDICAL SDN BHD (Malaysia)	
CATALOGUE NUMBER:	TG-0260, TG-0265, TG-0270, TG-0275, TG-0280, TG-0285, TG-0290	
CLASSIFICATION:	<ul style="list-style-type: none"> - Class IIa Medical Device in accordance with MDD 93/42/EEC - Personal Protective Equipment Category III according to Directive 89/686/EEC 	
METHOD OF STERILIZATION:	Gamma radiation	
CURRENT TECHNICAL STANDARDS ARE APPLICABLE TO THE DEVICE:	<ul style="list-style-type: none"> • in compliance with requirements of ASTM D3577, EN 455, resistant to penetration of viruses in accordance with ASTM F1671, resistant to penetration of chemicals according to EN 374-3, in accordance with EN 420, tested in accordance with EN 388 • Quality Assurance System: Manufacturing process in accordance with US FDA Quality System Regulation (QSR), BS EN ISO 9001 Quality System and EN ISO 13485 	
PERFORMANCE CHARACTERISTICS:	<ul style="list-style-type: none"> • Flexible, soft, with non-slip external surface, anatomically shaped, fit perfectly to the hand, providing the user with comfort of work and at the same time provide a protective barrier against microorganisms • Powder free - avoid skin irritation and postoperative complications caused by the powdering agent • Easy putting on thanks to the internal polymer layer • Designed for wide use in surgery 	
TECHNICAL DATA		
RAW MATERIAL:	natural rubber latex	
COLOUR:	natural latex, white and cream	
CUFF:	beaded	
POWDER:	powder-free	
PROTEIN LEVEL:	79 µg/g	
COVERAGE:	inner layer covered with polymer	
AQL:	1,0	
RESIDUES FROM CHEMICAL AGENTS USED FOR PRODUCTION:	below the limit of detection, which reduces the risk of type IV allergy and skin irritation	

EXCELLENT GRIP IN DRY AND WET CONDITIONS:	reliable grip thanks to the micro-texture on the entire surface of the glove			
SHAPE:	anatomical			
INDIVIDUAL PACKAGING:	double-packed gloves - inner paper packaging with glove size marking and distinguishing left and right hands, external packaging - film			
INTERMEDIATE PACKAGING:	50 pairs in the dispenser (4 dispensers in a carton)			
MARKING OF INDIVIDUAL AND INTERMEDIATE PACKAGING:	name of gloves, type, size, production date / series, expiry date, manufacturer's name			
SHELF LIFE:	5 years			
SIZES:	6 – 9			
DETAILED DIMENSIONS / SPECIFICATION:	SIZE	REF	WIDTH (mm)	LENGTH (mm)
	6	TG-0260	77±5	min. 280
	6½	TG-0265	83±5	min. 280
	7	TG-0270	89±5	min. 280
	7½	TG-0275	95±5	min. 280
	8	TG-0280	102±6	min. 280
	8½	TG-0285	108±6	min. 280
	9	TG-0290	114±6	min. 280
THICKNESS:	PART OF GLOVE		SINGLE WALL (mm)	
	finger (13mm from the tip)		0,16±0,02	
	palm (in the middle part)		0,14±0,02	
	cuff (25mm from the end of the cuff)		0,10±0,02	
PHYSICAL PROPERTIES:	PARAMETER	BEFORE AGING		AFTER AGING
	force at break (N)	min. 9		min. 9
	tensile strength (MPa)	min. 24		min. 18
	elongation at break (%)	min. 750		min. 560
BASED ON:	Technical Data Sheet of: TG Medical SDN BHD (Malaysia)			

TG MEDICAL**TOP QUALITY, TOP EFFICIENCY****TG MEDICAL SDN. BHD.****The World's Largest Rubber Glove Manufacturer****GOOD HEALTH, SAFETY FIRST & BE HONEST**

(Company No. 283358-W)

(GST ID: 001289224192)

A member of Top Glove Corporation Bhd, a Public Listed Company on Bursa Malaysia & Singapore Exchange.

FACTORY 3

: Lot 5091, Jln Teratai, 5th Miles, Off Jln Meru, 41050, Klang, Selangor D.E. Malaysia.

☎ +603-3392 7880/7350 📠 +603-3392 7229/9160 📠 +6012-2896 270 ✉ sales@topglove.com.my 🌐 www.topglove.com

BUSINESS DIRECTION

: To Produce Consistently High Quality Gloves At Efficient Low Cost.

FACILITIES

: 34 Factories (Malaysia, Thailand & China), 581 Production Lines, 55.8 Billion Gloves Per Annum, 12,000 Employees.

MARKET

: Exports to 195 countries worldwide with Marketing Offices in the USA and Germany.

DECLARATION OF CONFORMITY

Original Manufacturer's Name : TG MEDICAL SDN. BHD
 Original Manufacturer's Address : Lot 5091, Jalan Teratai, 5th Mile, Off Jalan Meru,
 41050 Klang, Selangor D. E. Malaysia

European Authorized Representative: Top Glove Europe GmbH
 Bliersheimer Str. 80, D-47229 Duisburg
 Deutschland/Germany
 Tel.:+49-(0)2065-76421-0, Fax:+49-(0)2065-76421-19

Name of Device : Latex Surgical Gloves
 Type : Powdered and Powder Free Glove
 Classification : Class IIa, Sterile
 Conformity Assessment Procedure : Annex V
 Conformity Route : CE 0120

We herewith declare in our own responsibility that the above-mentioned product(s) with CE mark meet the provisions of the EC Council Directive 93/42/EEC 14th June 1993 concerned medical devices, amended by Council Directive 2007/47/EC. All supporting documentations are retained under the premise of manufacturer (head of Quality department).

EC Certificate(s) : MY99/51109
 EC Certificate(s) valid until : 14 September 2021
 Notified Body : SGS United Kingdom Ltd. Systems & Services
 Certification
 Competent Authority : Bezirksregierung Düsseldorf,
 Postfach 300865, 40408 Düsseldorf.
 Registration Date : 31 March 2010
 Registration No : DE/CA20/02-TOPGLOBEB-01/10

Date : 17th May, 2018



Name: Noor Akilah Bte Saidin
 Designation: DGM- RA
 (RA/DOC/030/04/2018)