TERANG NUSA
TOP QUALITY, TOP EFFICIENCY

TERANG NUSA (MALAYSIA) SDN. BHD.
GOOD HEALTH, SAFETY FIRST & BE HONEST

Registration No.
199101013885 (224197-U)
SST ID: D10-1808-22000001

A member of Top Glove Group: The World's Largest Manufacturer of Gloves
FACTORY 36 : 2, Jalan 8, Pengkalan Chepa 2 Industrial Zone, 16100 Kota Bharu, Kelantan D.N., Malaysia.
+609 774 7171/+603 3362 3098 +609 771 3565/+609 774 7757 +6012 2896 270
sales@topglove.com.my www.topglove.com

BRAND NAME:

dermagel micropren

PRODUCT DESCRIPTION

Type of the glove	Sterile powder-free surgical and protective gloves for single use
Intended use	Sterile, powder-free, synthetic polychloroprene surgical gloves intended to be worn by operating room personnel to prevent the transmission of infections or cross contamination between patient and user
Material	Synthetic polychloroprene
Donning powder	None
Colour	Tan
Shape	Anatomic, curved fingers, hand specific
Cuff	Beaded
External surface	Textured, polymerized
Internal surface	Layered polymer
Packaging	1 pair per pouch, 50 pairs per dispenser, 200 pairs per carton

PHYSICAL PROPERTIES

Size		5.5 *	6.0	6.5	7.0	7.5	8.0	8.5	9.0
Length [mm]	EN 455-2 normative value	250	260	260	270	270	270	280	280
	Spec. [min]	290	290	290	290	290	290	290	290
Width [mm]	EN 455-2 normative value	72 ±4	77 ±5	83 ±5	89 ±5	95 ±5	102 ±6	108 ±6	114 ±6
Thickness single wall [mm]	Middle finger [min]	0,18							
	Palm [min]	0,16							
	Cuff [min]	0,15							
Force at break [N]	Before aging EN 455-2 normative value	9,0							
	After aging EN 455-2 normative value	9,0							
Powder content [mg/glove]	EN 455-3 normative value	<2							

MANUFACTURING AND SAFETY STANDARDS

Manufacturer	Terang Nusa (Malaysia) Sdn. Bhd. 2, Jalan 8, Pengkalan Chepa 2, Industrial Zone 16100 Kota Bharu, Kelantan, Malezja	
EC Representative	Ulma International GmbH Pfaffenweg 35, 89231 Neu-Ulm, Niemcy	
Importer	Mercator Medical S.A. H. Modrzejewskiej 30 street 31-327 Cracow, Poland	
AQL	Manufacturing final release: G-I inspection level AQL 0.65 in accordance with ISO 2859-1.	
Latex protein content	N/A. Product does not contain natural rubber latex.	
Sterilization	Irradiation / Gamma (R)	
Classification	**Medical Device:** class IIa Rule classification acc. to declaration of conformity	**Personal Protective Equipment:** Category III (Regulation (EU) 2016/425) Type B (EN ISO 374-1)
Conformity assessment body	TÜV SÜD Product Service GmbH, No 0123 Ridlerstraβe 65, 80339, Munich, Germany	SATRA Technology Europe Limited, No 2777 Bracetown Business Park, Clonee, D15YN2P, Ireland
Product compliances	EN 455-1, EN 455-2, EN 455-3, EN 455-4, EN ISO 15223-1, EN ISO 20417, EN 556-1, EN ISO 11737-1, EN ISO 11737-2, EN ISO 11137-1, EN ISO 11137-2, EN ISO 14971, EN ISO 10993-1, EN ISO 10993-5, EN ISO 10993-10, EN ISO 10993-11, EN ISO 10993-23, EN ISO 11607-1, EN ISO 11607-2	EN ISO 374-1, EN ISO 374-2, EN ISO 374-4, EN ISO 374-5, EN 16523-1, EN ISO 21420, EN 421 (excluding 4.3)
Quality compliances	EN ISO 13485, ISO 9001	
Viral test permeation	Test in accordance with EN ISO 374-5 (ISO 16604).	
Bacteria and fungi permeation	Test in accordance with EN ISO 374-5 (EN ISO 374-2).	
Chemotherapy drugs permeation test	Test in accordance with ASTM D6978.	
Chemical substances permeation test	Test in accordance with EN 16523-1.	
Radioactive contamination protection test	Test in accordance with EN 421 – protection against radioactive contamination only.	
Biocompatibility/ biological evaluation	Test in accordance with EN ISO 10993-5. No cytotoxic evidence observed. Test in accordance with EN ISO 10993-10. No skin irritation and sensitization evidence observed. Test in accordance with EN ISO 10993-11.	
REACH	The product does not contain substances listed in candidate list according to Regulation (EC) 1907/2006.	

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STORAGE AND DISPOSAL

Long-term storage instructions	It is recommended to store the gloves in dry place, in the temperature of 5-35°C and to protect them against direct sunlight. Keep the gloves in a distance of not less than 1m from heating devices, sources of fire and ozone. Do not keep in direct vicinity of solvents, oils, fuels and lubricants.
Transport instructions	Transport in conditions ensuring an appropriate hygienic standard, protecting the product against dirt. The product is not thermolabile - changing conditions regarding temperature or humidity in the short-term transport period do not affect the usability of the product or its properties or safety of use in any way. The product does not require transport in controlled conditions in terms of temperature and humidity (confirmed on the basis of accelerated aging tests and risk analysis).
Shelf life	5 years from manufacturing date
Product disposal	Used product should be treated as contaminated material, therefore local regulations regarding the disposal of such materials should be applied.
Packaging disposal	Master packaging (carton, dispenser) is made of homogeneous material, does not contain any foil elements, does not contain any different type of materials, does not need to be separated into fractions. Packaging is 100% recyclable, in accordance with local regulations. Unit packaging (outer envelope and inner envelope) is to be regarded as contaminated medical material and local regulations for the handling of such materials must be followed.

PRODUCT REFERENCES

Size / REF number

5.5*	6.0	6.5	7.0	7.5	8.0	8.5	9.0
RC40001055_0687	RC40001060_0687	RC40001065_0687	RC40001070_0687	RC40001075_0687	RC40001080_0687	RC40001085_0687	RC40001090_0687

* size available on request

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