TECHNICAL DATA SHEET

dermagel basic

PRODUCT DESCRIPTION

Type of the glove	Sterile powder-free surgical and protective gloves for single use
Intended use	Sterile, surgical and protective gloves intended to be worn on hand of healthcare personnel, operating room personnel and similar personnel to prevent contamination between the healthcare or similar personnel and the patient's body, fluids, waste, or environment during surgical procedure. Chemo-risk gloves designed for protection while working with the administration of chemotherapy drugs. Single use.
Material	Natural rubber latex
Donning powder	None
Colour	Creamy white
Shape	Anatomic, curved fingers, hand specific
Cuff	Beaded R/L and size marking at cuff
External surface	Textured (microtextured finger and inner side of the hand), polymer coated
Internal surface	Polymer coated
Packaging	1 pair per pouch, 50 pairs per dispenser, 400 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]	255	260	265	270	270	270	280	280
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]	0,13							
Force at break [N] Minimum	Before aging EN 455-2 normative value	9,0							
	After aging EN 455-2 normative value	9,0							
Ultimate Elongation [%] Minimum	Before aging ASTM D 3577 normative value	750							
	After aging ASTM D 3577 normative value	560							
Powder content [mg/glove]	EN 455-3 normative value	<2							
Latex protein content [µg/g glove]	EN 455-3 modified Lowry's assay	<50							

MANUFACTURING AND SAFETY STANDARDS

Manufacturer	Guilin HBM Health Protections Inc. No. 1-2, Shuijing East Road Economic & Technological Development Area 541805 Guilin, Guangxi, China	
Authorized Representative	HBM Medical Coliemore House, Coliemore Road Dalkey, Co Dublin A96 A8D5 Ireland	
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.	
Sterilization	Irradiation / E-beam (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	BSI Group The Netherland B.V., Notified Body No 2797 Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, Netherlands	Module B: ANCCP Certification Agency Srl, Notified Body No 0302 Via Dello Struggino, 6,57121 – Livorno, Italy Module D: Satra Technology Europe Ltd, Notified Body No 2777 Bracetown Business Park, Clonee, Dublin 15, Dublin, Ireland

Product compliances	EN 455-1, EN 455-2, EN 455-3, EN 455-4, ISO 2859-1, EN ISO 15223-1, EN ISO 20417, EN ISO 14971, EN ISO 10993-1, EN ISO 10993-5, EN ISO 10993-10, EN ISO 10993-11, EN ISO 10993-23, EN 556-1, EN ISO 11737-1, EN ISO 11737-2, EN ISO 11137-1, EN ISO 11137-2, 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
Quality management standards	EN ISO 13485, ISO 9001, ISO 14001	
Viral test penetration	Test in accordance with EN ISO 374-5 (ISO 16604) and ASTM F1671.	
Bacteria and fungi penetration	Test in accordance with EN ISO 374-5 (EN ISO 374-2).	
Synthetic blood penetration	Test in accordance with ASTM F1670.	
Chemotherapy drugs permeation test	Test in accordance with ASTM D6978.	
Chemical substances permeation test	Test in accordance with EN 16523-1.	
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.	
Production technology	Chlorine-free production process.	
REACH	The product does not contain substances listed in candidate list according to Regulation (EC) 1907/2006.	

STORAGE AND DISPOSAL

Long-term storage instructions	It is recommended to store the gloves in dry place, in the temperature of 5-40°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	3 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
RC10082055_2937	RC10082060_2937	RC10082065_2937	RC10082070_2937	RC10082075_2937	RC10082080_2937	RC10082085_2937	RC10082090_2937

* size available on request

Date: 29.05.2025, Rev. 1.0

2937