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PRODUCT INFORMATION
Nitrile Protective Glove Dermagrip Ultra LT

Nitrile protective gloves for use with cytostatics and microbiological agents

Summary

Maximum protection and comfortable to wear: Type-tested and certified as complex PPE[1)] of the highest category III; very good grip due to polymer coating on working side; very smooth on donning side; good tactile sensitivity; ambidextrous; textured surface on fingers and short beaded cuff (glove length 240 mm); AQL[2)]=1,5
Area of application: Protective gloves for handling cytostatics, CMR drugs (e.g. cytostatics, virostatis) and microorganisms & viruses[3)].
Protective properties: Protection from all CMR pharmaceuticals and chemicals cannot be guaranteed!
Glove replacement interval: Recommendation for cytostatics for Germany, in accordance with M 620, BGW and DGOP: Change every 30 minutes. For biological substances after every work cycle. Immediately in case of visible contamination. Single use!
Protective glove material: Nitrile, latex-free.
Before use: Check for damage! Do not use damaged gloves!
Disposal: Assignment of waste to European waste codes (EWC) for human or animal health care and / or related research, based on directive 2000/532/EC.

[1)] Personal protective equipment – 98/686/EEC. [2)] Acceptable quality level (Water test in accordance with QCTM 0053).
[3)] Carcinogenic mutagenic reproductive toxic

Versions

Size		S or 6	M or 7	L or 8	XL* or 9
Item No .	PU= 250 / 240* pieces	5010	5015	5020	5025*
	PU= Box with 8x dispenser of 50 pieces	5011	5016	5021	5026
	Wall mounted for dispenser box	per 1 box: 5050		per 1 box: 5051	

Flexibility

Dexterity tested in accordance with EN 420

Performance level	Smallest diameter[1)]
Level 5 (best level)	5 mm

[1]: Smallest diameter of the pin, to meet the test conditions.

Material

100 % Nitrile (Acrylonitrile butadiene)	
Colour	blue, powder-free in accordance with TRGS 540

Material thickness

Measuring points	Material thickness (measured twice)
Finger, 15 mm from the end of the tip	≥ 0,14 mm
Middle of the palm	≥ 0,12 mm
Shaft, 25 mm from the end shaft	≥ 0,10 mm

Protection from mechanical hazards

Mechanical hazards tested in accordance to EN 388 (12.03).

Requirements	Performance level
Abrasion resistance (1-4)	0
Cut resistance (1-5)	0
Tear resistance (1-4)	0
Stab resistance (1-4)	0

[1]: Movement of a chemical and/or microorganisms through porous material on a non-molecular level.

Protection against bacteriological hazards

Penetration[1] in accordance to EN 374-2 (12.03) fulfilled.

Protection against chemical hazards

Permeation[1] tested for numerous chemicals in accordance with EN 374 Part 3 (12/03). Breakthrough times[2] [min] / performance classes[3] (1-6) were established for the following chemicals:

Chemicals	Breakthrough time [min]	Performance level
Carboplatin 10 mg/ml	> 120	4
Carmustin 100 mg/ 25 ml	> 60	3
Cisplatin 50 mg/ 100 ml	> 120	4
Cyclophosphamide Monohydrate 500 mg/ 25 ml	> 60	3
5-Fluorouracil 1,5 mg/ml	> 120	4
Sulphuric acid 96%	> 30	2
Sodium hydroxide 40%	> 60	3
Isopropanol 70%	> 30	2
Glutaraldehyde 5%	> 60	3
Diethylamin (unverdünnt)	> 30	2
Daunorubicin 150 mg/ ml	> 120	4
Doxorubicin chlorhydrate 1mg/ ml	> 60	3
Etoposide 20 mg/ml	> 60	3
Paclitaxel 6 mg/ 50 ml	> 60	3
Thiotepa	> 60	3
Dacarbazine 10 mg/ ml	> 60	3
Ifosfamide 50 mg/ ml	> 30	2
Mitoxantron 2mg / ml	> 120	4
Vincristin 1 mg/ ml	> 120	4
Mitomycin 250 mg / 25 ml	> 30	2

[1]: Movement of a chemical through a material on a molecular level. [2]: At a permeation rate of 1 µg/min·cm²
[3]: The performance class does not reflect the actual duration of protection at the workstation, because they may be affected by temperature and abrasion!

Protection against bacteriological hazards

Penetration[1)] requirements met in accordance with EN 374 Part 2 (12/03). Test results as follows:

Feature	Present?
Tears (visual)	No
Cracks (visual)	No
Holes (visual)	No
Air bubbles (air leakage test)	No

Additional requirements for medical gloves

EN 455:2000 – Part 1: Requirements and tests for freedom from holes

EN 455:2000 – Part 2: Requirements and testing for physical properties

EN 455:2000 – Part 3: Requirements and testing for biological evaluation

Additional test in accordance to ASTM D 6319

Standard Specification for Nitrile Examination Gloves for Medical Applications

Quality management

Our **quality management system** is **tested and certified** by TÜV Management Service GmbH (a certification body accredited by the German Accreditation Council) in compliance with DIN EN ISO 9001:2008. Regular **audits and production site inspections** guarantees the quality of our products.

Storage and transport conditions

Dark (protect from direct UV light and sunlight)
Cool (+5 to +40°C) , dry
No contact with pointed and / or sharp objects

Shelf life

5 years from date of manufacture

CE-Marking and notified body

CE-marking in accordance to PPE guideline 89/686/EEC for complex PPE category III.

Notified body: BSI, Kitemark Court, Davy Avenue, Milton Keynes, MK5 8PP, Great Britain

Manufacturer

WRP Asia Pacific SDN BHD, Lot 1, Jalan 3; Kawasan Perusahaan, Bandar Baru Salak Tinggi; Sepang, Selangor Darul Ehsan, Selang 43900; Malaysia

Distributor

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