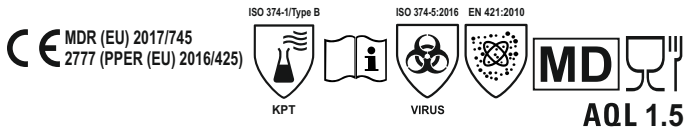


GRANBERG 633

REF 114.633-S-XL

PRODUCT-SPECIFIC INFORMATION ON THIS PAGE ONLY

Disposable Examination and Protective Gloves Magic Touch® by Granberg. Nitrile, non-sterile, powder-free. Black colour.



EN ISO 21420:2020

ASTM D6978

Available sizes	S	M	L	XL
	6/7	7/8	8/9	9/10

	EN ISO 374-1:2016+A1:2018 Type B	Permeation Performance Level	Measured Breakthrough Time (minutes)	EN ISO 374-4:2019 Mean Degradation (%)
K	40% Sodium Hydroxide	6	> 480	-25.7
P	30% Hydrogen Peroxide	2	> 30	44.8
T	37% Formaldehyde	5	> 240	-17.1

Chemotherapy Drugs tested in accordance with ASTM D6978.

Chemotherapy Drug in accordance with ASTM D6978	Minimum breakthrough detection time in minutes
Carmustine, 3.3 mg/ml (3,300 ppm)	12.9
Cisplatin, 1 mg/ml (1,000 ppm)	> 240
Cyclophosphamide, 20 mg/ml (20,000 ppm)	> 240
Dacarbazine, 10 mg/ml (10,000 ppm)	> 240
Doxorubicin HCl, 2 mg/ml (2,000 ppm)	> 240
Etoposide, 20 mg/ml (20,000 ppm)	> 240
Fluorouracil, 50 mg/ml (50,000 ppm)	> 240
Methotrexate, 25 mg/ml (25,000 ppm)	> 240
Mitomycin C, 0.5 mg/ml (500 ppm)	> 240
Paclitaxel (Taxol), 6 mg/ml (6,000 ppm)	> 240
Thiotepa, 10 mg/ml (10,000 ppm)	48.7
Vincristine Sulfate, 1 mg/ml (1,000 ppm)	> 240

This product is **Category III** Personal Protective Equipment as per Regulation (EU) 2016/425 and complies with standards: EN ISO 21420:2020, EN ISO 374-1:2016+A1:2018, EN ISO 374-5:2016, EN 421:2010 (excluding clause 4.3).

Notified Body responsible for EU Type Examination (**Module B**) and quality assurance of the production process (**Module D**): SATRA Technology Europe Ltd. (**NB No. 2777**), Bracetown Business Park, Clonee, D15YN2P, Republic of Ireland.

This product is classified as Class I Medical Device according to Annex VIII of the Regulation (EU) 2017/745 and complies with standards: EN 455-1, EN 455-2, EN 455-3, EN 455-4, ISO 15223-1:2021.

EU Declaration of Conformity: www.granberg.no/search

User Manual issue date: 04.10.2024

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EN USER MANUAL FOR DISPOSABLE PROTECTIVE GLOVES CATEGORY III and MEDICAL DEVICE

The User Manual should be used with product-specific information.

User Instructions should be read before using.

INTENDED USE

Powder-free examination and protective disposable nitrile gloves are intended for use in the medical field to protect patients and users from cross-contamination. These gloves are also intended to protect against certain chemicals, microorganisms, and radioactive contamination, where hand protection is needed. Foodstuff-approved gloves are marked with relevant food pictograms and comply with relevant EU Regulations. Gloves should be used only according to their intended purpose.

WARNINGS, PRECAUTIONS AND CONTRAINDICATIONS OF USE

This information does not reflect the actual duration of protection in the workplace and the differentiation between mixtures and pure chemicals and other factors influencing the performance such as temperature, abrasion, degradation etc. The chemical resistance has been assessed under laboratory conditions from samples taken from the palm only (except in cases where the glove is equal to or over 400 mm - where the cuff is tested also) and relates only to the chemical tested. It can be different if the chemicals used in a mixture. It is recommended to check that the gloves are suitable for the intended use because the conditions at the workplace may differ from the type test depending on temperature, abrasion, and degradation. When used, protective gloves may provide less resistance to a dangerous chemical due to changes in physical properties. Movements, snagging, rubbing, degradation caused by chemical contact, etc., may reduce the actual use time significantly. For corrosive chemicals, degradation can be the most important factor to consider in the selection of chemical-resistant gloves. Degradation levels (EN ISO 374-4:2019) indicate the change in puncture resistance of the gloves after exposure to the challenge chemical. The penetration resistance has been assessed under laboratory conditions and relates only to the tested specimens. These gloves do not protect against mechanical risks and ionizing radiation. Do not use if the glove is visibly torn, frayed or damaged. Change glove after each patient. Always select the correct size glove for your hand. For Single Use only. If re-used, the risk of contamination and infection increases due to improper cleaning processes; and increased risk of holes and tear during re-use due to weakening of gloves by cleaning processes. Poorly-fitting gloves will greatly reduce dexterity and cause fatigue. Using the wrong glove size leads to inadequate hand protection. Components used in glove manufacturing may cause allergic reactions in some users. If allergic reactions occur, seek medical advice immediately. The use of the device is contraindicated for medical conditions which require an examination, a diagnostic or therapeutic procedure on breached/compromised skin and/or under sterile conditions. Persons who are known to be sensitive with chemical additives should consider using this glove. Where relevant, a list of substances contained in the glove that are known to cause allergies, per listed in Annex G of EN ISO 21420:2020, shall be supplied on request.

ASTM D6978 - Gloves used for protection against chemotherapy drug exposure should be selected specifically for the type of chemicals being used. Due to the variety and concentration of chemotherapy drugs used in treatments, the resistance table shown does neither warrant nor imply the safe use of gloves against chemotherapy drug resistance in every case. The safe use of the glove in chemotherapy treatment is solely the decision of clinicians authorized to make such a decision.

PRODUCT INSTRUCTION FOR USE

Before use, after donning, and during use inspect the gloves for any defect or imperfections and discontinue use immediately if signs of tearing, swelling or degradation, or any damage appear. Dry hand before donning. Ensure chemicals or residuals cannot enter through the cuff. For donning, hold the glove by the bead with one hand. Align the glove thumb with your other hand thumb and slide your hand into the glove, one finger into each glove finger. Pull by the glove palm to get a good fit. Don the other glove by the same procedure. Doffing, hold glove bead and pull toward the finger until the glove come off. When an indication for hand hygiene precedes a contact that also requires glove usage, hand rubbing or hand washing should be performed before donning gloves and after removing gloves.

DISPOSAL

Used gloves can be contaminated and must be disposed of under hospital policy and/or local regulation.

STORAGE

Store in a cool and dry place in its original package. Recommended to store at room temperature prevailing in respective countries. Opened boxes should be kept away from fluorescent and sunlight. Keep the gloves away from ozone, heating devices, and the source of the fire. Gloves are packed in a dispenser box suitable for transport. Keep the gloves in the box when not in use. The shelf life for products stored as recommended is mentioned on each package. Service life cannot be specified and depends on the application and responsibility of the user to determine the suitability of the glove for its intended use.

REPORTING OF INCIDENTS

In case of any serious incident occurred with the use of this device, please report it to the manufacturer and the competent Authority.

Further information can be obtained from the manufacturer, please contact Granberg AS.

EXPLANATION OF SYMBOLS AND PICTOGRAMS USED

Protective gloves against dangerous chemicals and microorganisms - Part 1: Terminology and performance requirements for chemical risks. EN ISO 374-1:2016+A1:2018. Definition of breakthrough time through the glove palm (1 µg/cm²/min). Type A > level 2 for 6 chemicals, Type B > level 2 for 3 chemicals, Type C > level 1 for 1 chemical (no code under pictogram).

 ABCDEF GHI JKLMNPST	A: Methanol B: Acetone C: Acetonitrile D: Dichloromethane E: Carbon disulphide F: Toluene G: Diethylamine H: Tetrahydrofuran I: Ethyl acetate	J: n-Heptane K: Sodium hydroxide 40% L: Sulphuric acid 96% M: Nitric acid 65% N: Acetic acid 99% O: Ammonium hydroxide 25% P: Hydrogen peroxide 30% S: Hydrofluoric acid 40% T: Formaldehyde 37%	<table><tr><th>Permeation Performance Level</th><th>Measured Breakthrough Time (minutes)</th></tr><tr><td>1</td><td>> 10</td></tr><tr><td>2</td><td>> 30</td></tr><tr><td>3</td><td>> 60</td></tr><tr><td>4</td><td>> 120</td></tr><tr><td>5</td><td>> 240</td></tr><tr><td>6</td><td>> 480</td></tr></table>	Permeation Performance Level	Measured Breakthrough Time (minutes)	1	> 10	2	> 30	3	> 60	4	> 120	5	> 240	6	> 480
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Additional information on chemical resistance obtainable from manufacturer.																	
 VIRUS	Protection against bacteria, fungi and viruses		Fragile, handle with care		Raw material latex												
 VIRUS	Protection against bacteria and fungi, not tested against viruses		Keep away from sunlight		Do not contain natural rubber												
 EN 421:2010	Protection against bacteria and fungi, not tested against viruses		Keep dry		Contains potential Type IV chemical allergens												
 EN 421:2010	Protection against particulate radioactive contamination		Temperature limit		Corrugated cardboard												
	Suitable for contact with foodstuffs. Note: not all gloves that are suitable for handling food may be suitable for all types of food. Check the Food Declaration of Compliance.		Do not reuse		Non-corrugated paperboard												
	Manufacturer		Check User Instruction		Paper												
	Date of manufacture		Caution		Medical Device												
	Lot number		Non-sterile		Unique Device Identifier												
					Article number												

