

622  
REF 114.622

MAGIC TOUCH  
BY GRANBERG

PRODUCT-SPECIFIC INFORMATION

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



EN ISO 21420:2020

ASTM D6978-05

Table with sizes S, M, L, XL and available sizes 6/7, 7/8, 8/9, 9/10.

Table with columns: EN ISO 374-1:2016+A1:2018 (Type B), Permeation Performance Level, Measured Breakthrough Time (minutes), EN ISO 374-4:2019 Mean Degradation, %.



Latex free: yes.

This product is Category III Personal Protective Equipment as per Regulation (EU) 2016/425 and complies with standards: EN ISO 21420:2020, incorporating Amendment 1 from ISO 21420:2020/Amd.1:2022, EN ISO 374-1:2016+A1:2018, EN ISO 374-5:2016, EN 421:2010 (Radioactive contamination only).

Notified Body responsible for EU Type Examination (Module B): SATRA Technology Europe Ltd. (NB No. 2777), Bracetown Business Park, Clonoe, D15YN2P, Republic of Ireland. Notified Body responsible for Quality Assurance of the Production Process (Module D): BSI Group The Netherlands B.V. (NB No. 2797), Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands.

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

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User Manual issue date: 12.03.2024

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Chemotherapy Drugs tested in accordance with ASTM D6978-05.

Table with columns: Chemotherapy Drug in accordance with ASTM D6978-05, Minimum breakthrough detection time in minutes.

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.

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.

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.

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 bag suitable for transport.

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).

Table explaining symbols and pictograms: ISO 374-1 Type A, B, C; ISO 374-5:2016; EN 421:2010; ISO 374-4:2019; ISO 15804:2015; ISO 15805:2015; ISO 15806:2015; ISO 15807:2015; ISO 15808:2015; ISO 15809:2015; ISO 15810:2015; ISO 15811:2015; ISO 15812:2015; ISO 15813:2015; ISO 15814:2015; ISO 15815:2015; ISO 15816:2015; ISO 15817:2015; ISO 15818:2015; ISO 15819:2015; ISO 15820:2015; ISO 15821:2015; ISO 15822:2015; ISO 15823:2015; ISO 15824:2015; ISO 15825:2015; ISO 15826:2015; ISO 15827:2015; ISO 15828:2015; ISO 15829:2015; ISO 15830:2015; ISO 15831:2015; ISO 15832:2015; ISO 15833:2015; ISO 15834:2015; ISO 15835:2015; ISO 15836:2015; ISO 15837:2015; ISO 15838:2015; ISO 15839:2015; ISO 15840:2015; ISO 15841:2015; ISO 15842:2015; ISO 15843:2015; ISO 15844:2015; ISO 15845:2015; ISO 15846:2015; ISO 15847:2015; ISO 15848:2015; ISO 15849:2015; ISO 15850:2015; ISO 15851:2015; ISO 15852:2015; ISO 15853:2015; ISO 15854:2015; ISO 15855:2015; ISO 15856:2015; ISO 15857:2015; ISO 15858:2015; ISO 15859:2015; 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