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REF 114.621

MAGIC TOUCH BY GRANBERG

PRODUCT-SPECIFIC INFORMATION ON THIS PAGE ONLY

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

CE 2797 PPE Cat. III MD AQL 1.5 EAC

EN ISO 21420:2020 ASTM D6978-05

ISO 374-1/Type B ISO 374-5:2016 KPT VIRUS LOW DERMA Technology in Skin Protection

Table with columns: Available sizes, XS, S, M, L, XL. Rows: 5/6, 6/7, 7/8, 8/9, 9/10

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

Chemotherapy Drugs tested in accordance with ASTM D6978-05.

Table with 2 columns: Chemotherapy Drug in accordance with ASTM D6978-05, Minimum breakthrough detection time in minutes

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, EN ISO 374-1:2016+A1:2018, EN ISO 374-2:2019, EN 16523-1:2015+A1:2018, EN ISO 374-4:2019, EN ISO 374-5:2016.

Notified Body responsible for EU Type Examination (Module B): SATRA Technology Europe Ltd. (NB No. 2777), Bracetown Business Park, Clonee, 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 455-1:2020, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009, ISO 15223-1:2021.

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

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User Manual issue date: 14.06.2022

granberggloves.com



EN USER MANUAL FOR DISPOSABLE 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 where hand protection is needed.

WARNINGS AND PRECAUTIONS 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.

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. Change glove after each patient. Always select the correct size glove for your hand.

DISPOSAL

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

INGREDIENTS/HAZARDOUS COMPONENTS

Components used in glove manufacturing may cause allergic reactions in some users. If allergic reactions occur, seek medical advice immediately. 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.

STORAGE

Store in a cool and dry place in its original package. Opened boxes should be kept away from fluorescent and sunlight. Keep the gloves away from ozone, heating devices, and the source of the fire.

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 with columns: ISO 374-1 Type A, B, C, A: Methanol, B: Acetone, C: Acetonitril, 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 98%, O: Ammonium hydroxide 25%, P: Hydrogen peroxide 30%, S: Hydrofluoric acid 40%, T: Formaldehyde 37%

Additional information on chemical resistance obtainable from manufacturer.

Table with columns: Permeation Performance Level, Measured Breakthrough Time (minutes)

*Indicates that the glove falls below the minimum performance level as stated in EN ISO 374-1:2016+A1:2018 for the given individual hazard.

Grid of symbols and descriptions: ISO 374-5:2016 (Fragile, handle with care), VIRUS (Protection against bacteria, fungi and viruses), ISO 374-4:2019 (Protection against bacteria and fungi, not tested against viruses), Suitable for contact with foodstuffs, Manufacturer, Date of manufacture, Expiry date, LOT (Lot number), Do not contain natural rubber, Corrugated cardboard, Non-corrugated paperboard, Paper, Medical Device, Unique Device Identifier, Article number, Eurasian Conformity Mark, etc.

NO BRUKSANVISNING FOR ENGANGSHANSKER KATEGORI III og MEDISINSK UTSTYR

Brukerveiledningen skal brukes med produktspesifikk informasjon.

Brukerveiledningen må leses før bruk.

TILTENKT BRUK

Pudderfrie undersøkelse og beskyttende engangshansker av nitril tiltenkt til medisinsk bruk for å beskytte pasienter og brukere mot krysskontaminering. Disse hanskene er også ment for å beskytte mot visse kjemikalier, mikroorganismer der håndbeskyttelse er nødvendig.

ADVARSLER OG FORHOLDSREGLER VED BRUK

Denne informasjonen gjenspeiler ikke den faktiske varigheten av beskyttelse på arbeidsplassen og differensiering mellom blandinger og rene kjemikalier og andre faktorer som påvirker ytelsen som temperatur, siltasje, degradering etc. Kjemikaliebestandigheten har blitt vurdert under laboratorieforhold fra prøver tatt kun fra håndflaten (unntatt i tilfeller der hansen er lik eller lengre enn 400 mm. - hvor mansjettene også er testet) og gjelder kun kjemikaliet som er testet.

PRODUKTVEILEDNING FOR BRUK

Før bruk, etter påføring og under bruk, inspisere hanskene for eventuelle defekter eller ufullkommenheter, og avbryt bruken umiddelbart hvis tegn på riveskader, hevelser eller nedbrytning eller skade vises.

KASTING/KASSERING

Brukte hansker kan være forurenset og må kastes i henhold til sykehusets retningslinjer og/eller lokale forskrifter.

INGREDIENSER/FARLIGE KOMPONENTER

Komponenter som brukes i hanskeproduksjon kan forårsake allergiske reaksjoner hos noen brukere. Hvis allergiske reaksjoner oppstår, kontakt lege umiddelbart.

LAGRING

Oppbevares på et kjølig og tørt sted i originalpakningen. Åpnede bokser bør holdes unna fluoriserende lys og sollys.

RAPPORTERING OM ALVORLIGE HENDELSER

Hvis det oppstår en alvorlig hendelse med bruk av disse hanskene, vennligst rapporter det til produsenten og de ansvarlige myndigheter.

Ytterligere informasjon kan fås hos produsent, vennligst kontakt Granberg AS.

FORKLARING AV SYMBOLER OG PIKTOGRAMMER SOM BRUKES

Vernehansker mot farlige kjemikalier og mikroorganismer - Del 1: Terminologi og ytelseskrav for kjemiske risikoer. EN ISO 374-1:2016+A1:2018. Definisjon av gjennombruddstid gjennom hanskendeflatten (1 µg/cm²/min). Type A > nivå 2 for 6 kjemikalier, Type B > nivå 2 for 3 kjemikalier, Type C > nivå 1 for 1 kjemikalie (ingen kode under piktogram).

Table with columns: ISO 374-1 Type A, B, C, A: Metanol, B: Acetone, C: Acetonitril, D: Diklormetan, E: Karbondisulfid, F: Toluene, G: Dietylamin, H: Tetrahydrofuran, I: Etylacetat, J: n-Heptan, K: Natriumhydroksid 40%, L: Svovelsyre 96%, M: Salpetersyre 65%, N: Eddiksyre 99%, O: Ammoniumhydroksid 25%, P: Hydrogenperoksid 30%, S: Flussyre 40%, T: Formaldehyd 37%, Ytelsesnivå for gjennomtrengning, Målt gjennombruddstid (minutter)

*Indikerer at hansen faller under det minimum ytelsesnivå som angitt i EN ISO 374-1:2016+A1:2018 for den gitte individuelle faren.

Grid of symbols and descriptions: ISO 374-5:2016 (Beskyttelse mot bakterier, sopp og virus), VIRUS (Beskyttelse mot bakterier og sopp, ikke testet mot virus), ISO 374-4:2019 (Beskyttelse mot bakterier og sopp, ikke testet mot virus), Egnet for kontakt med matvarer, Produsent, Produksjonsdato, Utløpsdato, LOT (Lotnummer), Skjær, behandles forsiktig, Inneholder ikke naturgummi, Bølgepapp, Ikke bølgepapp, Papir, Medisinsk utstyr, Unik enhetsidentifikator, Artikkelnnummer, Råstoff lateks, EAC samsvarsmärke, etc.

