



- GB Freedom From Holes Guarantee AQL 0.65
BA Napestojanje Rupa Garantuje AQL 0.65
BG Гаранция За Отсъствие На Дупки AQL 0.65
CS Garancie Nepropnosti AQL 0.65
DE Garantie Lochfreiheit AQL 0.65
DK Fri For Huller Garanti AQL 0.65
EL Ελευθερία Από Όσες Έυθούρες AQL 0.65
FR Garantie Sans Trou AQL 0.65



- GB 100% Pneumatic Air Inflation Tested
BA 100% Testirano Vazduhom Pod Pritskom
BG Испитвани Чрез Надуване Със Съствен Въздух До 100%
CS 100% Testováno NaFouknutim Stlačenim Vzduchem
DE 100% Druckluftgetestet
DK 100% Testet For Pneumatisk Luftopustning
EL 100% Πνευματική Εμπύση Αερά Ελεγχόμενη
FR 100% Testé Par Conflament Pneumatique



- GB Damp Donning / Suitable For Double Gloving
BA Lako Navlačenje Kako Na Suhe Tako I Na Vlažne Ruke - Pogodne I Za Hiruske
BG Удобен За Поставяне На Влажни Ръце - Подходящи За Носене На Дъжд Члръца
CS Vlhké Navlékání - Vhodné Pro Aplikaci Drojných Rukavic
DE Zum Aufziehen Auf Feuchte Hände - Geeignet Für Doppelte Behandlung
DK Fugtig Påføring - Velegende Til Døbbelte Handsker
EL Υγρή Εμβύση/α - Κατάλληλη Για Διπλή Εμβύση Γαντιών
FR Enfilage Sur Mains Humides - Adapté Pour Double Gantage



- GB Fiber Free Easy Peel Pouch System
BA Jednostavno Otvaranje Pakovanja
BG Лесно За Отваряне Топлоизолитета Опаковка Без Влакна
CS Jednoduchý Peel Systém Obalu Bez Vlákna
DE Faserfrei, Leicht Zu Handhabende Peelbeutel
DK Fiberfrit Lettåbnet Poseystem
EL Χυφρό Ισος Συστημα Ουνετο Εκούδο Αποκόλλησης
FR Système Pochette Enlavage Facile Sans Fibres



- GB Ergonomic Fit Technology With Curved Fingers - Micro-textured
BA Anatomski Oblikovane Sa Zakrivljenim Prstima - Mikroteksturirane
BG Технология За Анатомично Прилягане С Извити Пърсти - Микротекстурирани
CS Ergonomicky tvarované Se Zakřivenými Prsty - Mikro-texturované
DE Ergonomische Passform Mit Vorgeformten Fingern - Mikrotexturiert
DK Ergonomisk Tilpasset Teknologi Med Buede Fingre - Mikro-tekstur
EL Εργονομική Τεχνολογία Προσαρμογή Με Καμπυλωμένα Δακτύλα - Μικρο-υφασμενα
FR Technologie Ergonomique Avec Digits Incurvés - Micro-texture



- GB LOW ENDOTOXIN - NON-PYROGENIC
BA NIZAK ENDOTOKSIN - NE-PYROGENSKI
BG НИСКА ЕНДОТОКСИН - НОН-ПИРОГЕННИ
CS NÍZKÁ ENDOTOXINU - NON-PYROGENNÍ
DE NIEDRIGES ENDOTOXIN - NICHT PYROGENISCH
DK LAV ENDOTOXIN - IKKE-PYROGENISK
EL ΧΑΜΗΛΕΣ ΕΝΔΟΤΟΞΙΝΗ - ΝΟΝ-ΠΥΡΕΤΟΓΕΝΟΝ
FR FAIBLE ENDOTOXINE - NON-PYROGÈNE



- GB Reinforced Cuff
BA Ojačan Rukav
BG Подсилен Маншет
CS Zesílená Manžeta
DE Verstärkte Stulpe
DK Forstærket Opslag

- HR Oslobođanje Od Odgovornosti Za Nastanak Rupa AQL 0.65
HU A 0.65 AQL Értékét Garatáljuk Lyukmentesség
IT Garanzia Dell'assenza Di Fori AQL 0.65
NL Vrijwaring Van Gat en Garantie AQL 0.65
NO Garantert Uten Hull AQL 0.65
PL Nieobecność Dziur Zagwarantowana AQL 0.65
RO Garanție împotriva Găurilor AQL 0.65
RU Гарантия Отсутствия Протечек AQL 0.65
SR Garancija Nepostojanja Rupa AQL 0.65
SV Garanterat Fri Från Hull AQL 0.65
TR Deliksizlik Garantisi AQL 0.65
UA Відсутність Отворів Гарантується На Рівні Якості Приймання 0,65

- HR Ispitano Na Napuhivanje 100 % Pneumatiskm Načinom
HU 100% Pneumatikus Levegő Befújásra Tesztelve
IT Testati Con Aria Compressa Al 100%
NL 100% Pneumatische Luchtinspuiting Getest
NO 100% Testet Ved Pneumatisk Luftinflasjon
PL 100% Kontrolni Testem Powietrzonym
RO Testat Pneumatic La Umflarea Cu Aer 100%
RU 100% Прохождение Теста Жакетом Воздухом
SR 100% Testirano Na Uduvanje Pneumatiskog Vazduha
SV 100% Tryckluftstestad
TR %100 Pnömatik Şişirme Testinden Geçirilmştir
UA 100 % Пневматичне Накчування Повітрям Перевірено

- HR Navlačenje Na Vlažne Ruke - Prikladno Za Dvosteuku Rukavice
HU Nedves Felvét - Dupla Rétegzés Is Megfelelő
IT Applicazione A Umido - Adatto Per Sistema A Doppio Guanto
NL Vochtorname - Geschikt Voor Dubbele Handschoenen
NO Å Ta Hanske På Fuktige Hender - Passer Ved Bruk Av Double Hansker
PL Z Możliwością Nakładania Na Wilgotne Dłonie - Odpowiednie Do Podwojnego
RO Echipare Umede / Potrivit Pentru Mâni Duple
RU Одежда На Влажные Руки - Подходит Для Системы Двойных Перчаток
SR Vlažno Navlačenje - Odgovarajuće Za Nošenje Dupli Rukavice
DE Zum Aufziehen Auf Feuchte Hände - Lampfuga Vid Användning Av Dubbla Handskar
TR Islak Ele Giyme - Çift Kat Eldiven Uygunlamasına Uygun
UA Легко Надягаються У Вологую Середовищі - Придатні Для Використання У

- HR Bez Vlákana, Jednostavno Skidanje, Sustav S Vrećicama
HU Rostmentes, Könnyen Levehető Tasakos Kézakítás
IT Astuccio Con Estrazione Semplificata, Senza Fibre
NL Vezelrijk Gemakkelijk Schil-zakstysteem
NO Fiberfritt Lettåbnet Pose-system
PL Bezpyłowy System Otwierania Koptek
RO Sistem Saculet Fără Fibre Cu Desprindere Ușoară
RU Безволокнистая Легкая Система Открытия Упакровки
SR Sistem Kese Bez Vlákana Lakog Odlepljivanja
SV System Med Fiberfria Lättåpnade Påsar
TR Fiber İçermeyen Kese Sistem
UA Проста Система Безволокнистого Терміну Заваренного Пакуку

- HR Ergonomsko Prianjanje - Tehnologija Prirodno Savijenog Ergonomskusk, Izschedesu Tehnologija Hujltott Ujjakkal - Mikrotexturált
IT Tecnologia Ergonomica Con Dita Ricurve - Micro-goffratura
NL Ergonomische Passvorm Technologie Met Gebogen Vingers - Micro-textuur
NO Ergonomisk Tilpasset Teknologi Med Buede Fingre - Mikrotekstur
PL Anatomycznie Kształt Z Zakrzywionymi Palcami - Mikrotekstura Na Całej Powierzchni
RO Tehnologie De Potrivire Ergonomică, Degate Curbat - Microtextură
RU Эргономичная Форма С Изогнутыми Пальцами - Микротекстурированные
SR Tehnologija Ergonomskog Naklapanja Sa Zakrivljenim Prstima - Mikroteksturirano
SV Teknologi Med Ergonomisk Passform Och Böjda Fingrar - Mikrotexturerade
TR Ergik Parmaklı Ergonomik Sistem - Mikro Dokulu
UA Технологія Ергономічної Посадки Із Зігнутими Пальцями - Мікротекстурована

- HR NISKI ENDOTOKSIN - NE-APIROGENE
HU ALACSONY ENDOTOXIN - NON-PIROGÉN
IT ENDOTOSSINA BASSA - NON-APIROGENO
NL LAEGE ENDOTOXINE - NIET-PYROGENE
NO LAV ENDOTOXIN - IKKE-PYROGENISK
PL LOW ENDOTOKSINY - NIE-PYROGENICZNY
RO JOS ENDOTOXINELE - NE-APIROGEN
RU НИЗКИЙ УРОВЕНЬ ЭНДОТОКСИНА - АПИРОГЕННО
SR NISKOENDOTOKSIN - NE-PIROGENETSKI
SV LÅG ENDOTOXIN - ISKE-PYROGENT
TR DÜŞÜK ENDOTOKSİN - OLMAYAN PİROGENİK
UA НИЗЬКИЙ ЕНДОТОКСИНИ - НЕПІРОГЕННІ

- EL Ενοχυμένη Μανβέτα
FR Brassard Renforcé
HR Ojačane Drukvice
HU Megerősített Mandzsetta
IT Polsino Rinforzato
NL Versterkte Manchet
NO Forsterket Mansjett
PL Wzmocniony Mankiet
RO Manșetă Întărită
RU Усиленная Манжета
SR Ojačana Manžeta
SV Förstärkt Krage
TR Desteklenmiş Manşet
UA Посилена Манжета

PRODUCT DESCRIPTION : Sterile, Powder Free Latex Surgical Gloves (Ntouch)

A) MEDICAL DEVICE DIRECTIVE (MDD)

- 1) This product is classified under Class IIa Medical Device per Rule 6 and Rule 7 of Annex IX, meets the provisions of the Council Directive 93/42/EEC, as amended by the Council Directive 2007/47/EC.
2) This product complies with European Standards EN 455-1:2000, EN 455-2:2015, EN 455-3:2015, and EN 455-4:2009.

B) EU TYPE-EXAMINATION

- 1) This product is classed as Category III of Personal Protective Equipment (PPE) according to PPE Regulation (EU) 2016/425 and has been shown to comply with this Regulation through the Harmonised European Standards BS EN 420:2003+A1:2009, EN ISO 374-1:2016 and EN ISO 374-5:2016.
2) Notified Body responsible for certification and Module B compliance is British Standard Institution (BSI) 0086, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP, United Kingdom.
3) Notified Body responsible for Quality Assurance of the Production Process (Module D) is British Standard Institution (BSI) 0086, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP, United Kingdom.
4) EU Declaration of Conformity is accessible at www.kossan.com.my

C) INDICATION FOR USE (IFU)

Surgical gloves are intended to be used once in an invasive procedure involving a single patient and permanently discarded after use. These gloves are worn on the hands of healthcare personnel to provide barrier protection from cross contamination between a patient and the healthcare personnel. These gloves are also intended to protect against risks associated with contact against certain chemicals, chemotherapy drugs, and microorganisms, where hand protection is of priority.

D) USAGE

For single use only. If re-used: Lost of sterility | Extremely high risk of cross-contamination | Deterioration of barrier protection | Deterioration of glove's properties | Lost of lot traceability

E) MARKING

- a) Micro Organism Hazards Pictogram: EN ISO 374-5:2016 Protect against Bacteria, Fungi and Virus. No penetration of bacteriophages through the specimen and the pictogram#1 is applied.
b) Chemical Hazards Pictogram: BS EN 16523-1:2015, Additional information on chemical resistance obtainable from manufacturer. EN ISO 374-1:2016 permeation levels are based on breakthrough times as follows:

Table with 2 columns: Performance Level, Breakthrough time (mins). Values range from >10 to >480.

This product complies with Type B requirements and the pictogram#2 is applied shall be used with reference to clause 6.2 of ISO 374-1.

F) PERFORMANCE AND LIMITATION OF USE

- a) This product had been tested in accordance with EN ISO 374-5:2016. Protection against bacteria and fungi - Pass Protection against viruses - Pass
b) Gloves had been tested in accordance with BS EN 16523-1:2015 resistance to permeation by chemicals and achieved the following performance levels:-

Table with 4 columns: Chemicals, Performance Level, Chemicals, Performance Level. Lists Sodium Hydroxide, Formaldehyde, Hydrogen Peroxide, Sodium Hypochlorite, Ethidium Bromide, Glutaraldehyde, Sulphuric acid, Isopropanol, Ammonium Hydroxide, Diethylamine.

- 1) This information does not reflect the actual duration of protection in the workplace and the differentiation between mixtures and pure chemicals.
2) 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 400mm - where the cuff is tested also) and relates only to the chemical tested. It can be different if the chemical used in a mixture.
3) 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.
4) When used, protective gloves may provide less resistance to the dangerous chemical due to changes in physical properties. Movements, snagging, rubbing, degradation caused by the chemical contact etc. may reduce the actual use time significantly. For corrosive chemicals, degradation can be the most important factor to consider in selection of chemical resistant gloves.
5) Before usage, inspect the gloves for any defect or imperfections.
6) This product had been tested in accordance with BS EN 374-4:2013 and achieved the following degradation results:-

Table with 4 columns: Chemicals, Mean Degradation %, Chemicals, Mean Degradation %. Lists Sodium Hydroxide, Formaldehyde, Hydrogen Peroxide, Sodium Hypochlorite, Ethidium Bromide, Glutaraldehyde, Sulphuric acid, Isopropanol, Ammonium Hydroxide, Diethylamine.

- 1) EN 374-4:2013 Degradation levels indicate the change in puncture resistance of the gloves after exposure to the challenge chemicals.
d) This product provides protection against Bacteria, Fungi and Virus. The gloves had been tested in accordance with ISO 16604:2014 to meet the requirements of BS EN ISO 374-5:2016 for resistance to penetration by blood-borne pathogens-test method using Phi-X174 bacteriophage.
e) The penetration resistance has been assessed under laboratory conditions and relates only to the tested specimen.
f) The gloves were found to meet with the REACH annex XVII requirements for Polycyclic Aromatic Hydrocarbons (PAHs).
g) Components used in glove manufacturing may cause allergic reactions in some users. If allergic reactions occur, seek for medical advice immediately.

G) CONTRAINDICATIONS

Healthcare personnel and patients with known allergy to chemicals and latex protein should avoid contact with rubber latex gloves.

H) WARNINGS

- 1) This product contains natural rubber latex which may cause allergic reactions, including anaphylactic responses.
2) Do not use if the sealed pouch is punctured, torn, or otherwise compromised.
3) Do not use if the glove is visibly torn, frayed, or damaged.
4) Do not re-sterilize.
5) Do not use for more than 60 minutes to reduce the risk of strain/fatigue on hands and loss of barrier protection.

I) Storage conditions

Store under cool and dry conditions. Avoid direct sunlight, and heat. Gloves are packed in dispenser which is suitable for transport. Keep the gloves in the box when not in use.

J) INSTRUCTION FOR USE

- 1. For maximum comfort, choose the gloves size most appropriate to your hands. As surgical gloves are hand-specific, donning the correct size will reduce the risk of strain/fatigue on hands during use.
2. Donning: Prior to donning, perform surgical hand scrub using antimicrobial solution and water. When donning, follow "closed donning" method as described below.
3. Discard the soiled gloves and change to new gloves immediately. As soon as any damage, puncture or tear (or non-integrity is suspected) is noticed, After inadvertent contact with contaminated/unsterile surface.
4. In order to reduce the risk of barrier failure and to ensure better protection during surgical procedures which extend beyond 60 minutes, users are advised to change gloves on hourly basis.
5. These gloves have been tested against chemotherapy drugs (refer Section N)

K) PRECAUTION FOR DISPOSAL

Dispose of soiled surgical gloves in accordance with relevant regulations pertaining to safe disposal of clinical waste.

L) CLOSED DONNING METHOD

- STEP 1: Remove the inner wrap from the pouch carefully without creasing the inner wrap. STEP 2: Gently lift the right and left side of the inner wrap. STEP 3: Un-flap the inner wraps from the corner. Donning Right-side : STEP 4: Use your left hand to pick the right-side of the glove by holding the cuff. STEP 5: Gently slip your fingertips into the glove, stretch the cuff over the fingers until it fit snugly over the hand. Donning Left-side : STEP 6: Use your right hand to pick the left-side of the glove by the cuff. STEP 7: Gently slip your fingertips into the glove, stretch the cuff over the fingers until it fit snugly over the hand.

M) SYMBOL USED

Table with 4 columns: Symbol, Title of Symbol, Description / Requirements, Information. Includes symbols for Manufacturer, Authorized representative, Date of manufacture, Use-by date, Batch code, Do not re-use, Latex, CE Mark, Keep Dry, Non-pyrogenic, Sterilized using irradiation, Do not use if package is damaged.

Note: This User Information is part of marking package and intended to provide general guideline only

N) SHELF LIFE

The shelf life of product is 4 years from date of manufacture.

O) ADDITIONAL INFORMATION

- 1) Tested for Use with Chemotherapy Drugs This product has been tested against chemotherapy drugs in accordance with EN 16523-1:2015, with following results:-

Table with 4 columns: Drugs, Performance Level, Drugs, Performance Level. Lists Carmustine, Cyclophosphamide, Doxorubicin Hydrochloride, Etoposide, 5-Fluorouracil, Paclitaxel, Thio-Tepa, Cisplatin, Dacarbazine.

2) Non-Pyrogenic/Low Endotoxin Content

This product is tested per European Pharmacopoeia, Monograph 2.6.14, "Bacterial Endotoxins", using Kinetic Turbidimetric Method. The endotoxin content shall not exceed the limit of 20 endotoxin units (EU)/pair of gloves, per EN 455-3 requirements.