

LATEX

Comfort-fit

Powder-free Examination Gloves



Recommended
for medical use



- Ideal glove thickness for vigorous procedures
- Cost saving alternative for supporting medical team
- Exceptional elongation & dexterity
- Snug fit ability
- Strong grip
- Renewable resource - natural rubber latex material
- Chemical resistant
- Recyclable packaging

PS54

Reference code: IMPS54Y

PRODUCT SPECIFICATION

(ASTM D6319 & EN 455)

Colour: Natural colour

Dimension (mm)	Spec	Typical	
		mm	mil
Cuff	Min. 0.04	0.05	2.0
Palm	Min. 0.05	0.06	2.4
Finger	Min. 0.06	0.08	3.1
Length	Min. 240	240 - 245	

Physical Properties

Unaged

Tensile strength (MPa)	Min. 18	28 - 32
Elongation (%)	Min. 500	500 - 540
Force at break (N)	Min. 6.0	6.0 - 6.3

Aged

Tensile strength (MPa)	Min. 14	29 - 33
Elongation (%)	Min. 400	460 - 500
Force at break (N)	Min. 6.0	6.0 - 6.3

PACKAGING INFORMATION

Case dimension (mm)	365 x 250 x 250
Box dimension (mm)	240 x 120 x 70
Packing mode	100 pcs / box, 10 boxes / carton

Maximum loading	20'GP	40'GP	40'HQ
	1215 cartons	2600 cartons	3000 cartons

PRODUCT ATTRIBUTES

Medical • Polymer coated • Smooth surface • Standard cuff 9.5" • AQL 1.5

iNtouch™



ISO 374-1/Type C



ISO 374-5:2016



NITRILE

Shield-aid

Powder-free Examination Gloves



Recommended
for medical use



- Cost saving alternative for supporting medical team
- Excellent film strength
- Excellent puncture resistance
- Customised fitting property, prevent hand fatigue
- Clear indication of tears and breaks
- Prevent type I hypersensitivity
- Chemical resistant
- Recyclable packaging

CS30

Reference code: IMCS30

PRODUCT SPECIFICATION

(ASTM D6319 & EN 455)

Colour: Natural colour, blue

Dimension (mm)	Spec	Typical	
		mm	mil
Cuff	Min. 0.04	0.05	2.0
Palm	Min. 0.05	0.06	2.4
Finger	Min. 0.06	0.08	3.1
Length	Min. 240	240 - 245	

Physical Properties		Unaged
Tensile strength (MPa)	Min. 18	28 - 32
Elongation (%)	Min. 500	500 - 540
Force at break (N)	Min. 6.0	6.0 - 6.3

		Aged
Tensile strength (MPa)	Min. 14	29 - 33
Elongation (%)	Min. 400	460 - 500
Force at break (N)	Min. 6.0	6.0 - 6.3

PACKAGING INFORMATION

Case dimension (mm)	250 x 240 x 245
Box dimension (mm)	240 x 120 x 45
Packing mode	100 pcs / box, 10 boxes / carton

Maximum loading	20'GP	40'GP	40'HQ
	1860 cartons	3960 cartons	4410 cartons

PRODUCT ATTRIBUTES

Medical • Chlorinated • Fingertips textured • Standard cuff 9.5" • AQL 1.5



iNtouch™

 STRETCHING LIMITS • SINCE 1979	PRODUCT SPECIFICATION	Doc No PS-0003	
		Rev 2	Page 2 of 2

Product	:	Non-Sterile, Ambidextrous, Finger-Textured Surface, Powder Free Nitrile Examination Gloves
Color	:	White, Blue, Black
Product Code	:	OCPFNF-BF-3.0 (EB53001JA-BF), OCPFNF-WC-3.0 (EB53002JA-WC), OCPFNF-BT-3.0 (EB53002JA-BT), OCPFNF-KB-3.0 (EB53001JA-KB)
Reference Code	:	CS30-BF, CS30-WC, CS30-BT, CS30-KB
Grade	:	AQL 1.5
Inspection Method	:	ASTM D6319 and EN 455-1/2/3 (Current Version)
Quality Assurance	:	Manufactured under ISO 13485, CAN/CSA ISO 13485, ISO 9001 and US FDA QSR Quality Management System

No	Test	Particular		Specification	In-house Inspection Level / AQL
1	Dimension (mm)	Width	Extra Small	75 ± 5	S2/AQL 4.0
			Small	85 ± 5	
			Medium	95 ± 5	
			Large	106 ± 5	
			Extra Large	116 ± 5	
			Extra Extra Large	125 ± 5	
		Length		Min. 240	
		Thickness (Single Wall)	Cuff (25 ± 5 from bead)	Min. 0.04	
			Palm (center of palm)	Min. 0.05	
			Finger (13 ± 3 from tip)	Min. 0.06	
2	Physical Properties	Unaged (ASTM)	Tensile Strength (MPa)	Min. 18	S2/AQL 4.0
			Elongation at Break (%)	Min. 500	
		Unaged (EN)	Force at Break (N)	Min. 6.0	n = 13 (Median Value)
		Aged (ASTM)	Tensile Strength (MPa)	Min. 14	S2/AQL 4.0
			Elongation at Break (%)	Min. 400	
		Aged (EN)	Force at Break (N)	Min. 6.0	n = 13 (Median Value)
3	Freedom from Holes				GI/AQL 1.5
4	Visual Defects (Major)	Crack Line, Deformed Gloves, Dirt/Stain ≥1mm², Discoloration, Flow Mark, Incomplete Beading, Lump ≥2mm², Mix Size, Mix Type, Powder Mark, Polymer Mark, Sticky Gloves/Sticky Pleat ≥5mm, Thin Spot/Fish Eye			GI/AQL 2.5
5	Visual Defects (Minor)	Blister, Dirt/Stain <1mm², Lump <2mm², Poor Beading, Sticky Pleat <5mm			GI/AQL 4.0
6	Powder Residue	Max 1.5 mg/glove			n = 5

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 STRETCHING LIMITS • SINCE 1979	PRODUCT SPECIFICATION	Doc No	
		PS-1025	
		Rev	Page
		1	2 of 2

Product	:	Non-Sterile, Ambidextrous, Smooth Surface, Powder Free Polymer Coated, Natural Rubber Latex Examination Gloves
Color	:	Natural
Product Code	:	OLPYS-NA-5.4 (ER35401AA-NA)
Reference Code	:	PS54Y
Grade	:	AQL 1.5
Inspection Method	:	ASTM D3578 and EN 455-1/2/3 (Current Version)
Quality Assurance	:	Manufactured under ISO 13485, CAN/CSA ISO 13485, ISO 9001 and US FDA QSR Quality Management System

No	Test	Particular		Specification	In-house Inspection Level / AQL
1	Dimension (mm)	Width	Extra Small	75 ± 5	S2/AQL 4.0
			Small	85 ± 5	
			Medium	95 ± 5	
			Large	106 ± 5	
			Extra Large	116 ± 5	
			Extra Extra Large	125 ± 5	
		Length		Min. 240	
		Thickness (Single Wall)	Cuff (25 ± 5 from bead)	Min. 0.06	
Palm (center of palm)	Min. 0.08				
Finger (13 ± 3 from tip)	Min. 0.10				
2	Physical Properties	Unaged (ASTM)	Tensile Strength (MPa)	Min. 18	S2/AQL 4.0
			Elongation at Break (%)	Min. 650	
		Unaged (EN)	Force at Break (N)	Min. 6.0	n = 13 (Median Value)
			Aged (ASTM)	Tensile Strength (MPa)	Min. 14
		Elongation at Break (%)		Min. 500	
		Aged (EN)	Force at Break (N)	Min. 6.0	n = 13 (Median Value)
3	Freedom from Holes				GI/AQL 1.5
4	Visual Defects (Major)	Crack Line, Deformed Gloves, Dirt/Stain ≥1mm², Discoloration, Flow Mark, Incomplete Beading, Lump ≥2mm², Mix Size, Mix Type, Powder Mark, Polymer Mark, Sticky Gloves/Sticky Pleat ≥5mm, Thin Spot/Fish Eye			GI/AQL 2.5
5	Visual Defects (Minor)	Blister, Dirt/Stain <1mm², Lump <2mm², Poor Beading, Sticky Pleat <5mm			GI/AQL 4.0
6	Powder Residue	Max 1.5 mg/glove			n = 5
7	Protein	Max 50 µg/g (for EN Testing Method)			n = 8
		Max 50 µg/dm² (for ASTM Testing Method)			n = 3

iNtouch™ POWDER FREE NITRILE EXAMINATION GLOVES

EN : USER INFORMATION
FR : INFORMATIONS DE L'UTILISATEUR
RO : INFORMAȚII UTILIZATOR

Available Size

XS
S
M
L
XL

ISO 374-1/Type B



KPT

ISO 374-5: 2016



VIRUS

EN POWDER FREE NITRILE EXAMINATION GLOVES • Non sterile • Single Use • Recommended for medical use

Medical Device Regulation (EU) 2017/745 & Personal Protective Equipment Regulation (EU) 2016/425 (Category III) • Medical Devices Regulations 2002 (SI 2002 No. 618, as amended) (UK MDR 2002) • EU Notified Body for (Module B) and Module C2: SATRA Technology Europe Limited (2777) • UK Approved Body for (Module B) and Module C2: SATRA Technology Center Limited (AB0321) • EU Declaration of Conformity • UK Declaration of Conformity is accessible at www.intouchcares.com • This information does not reflect the actual duration of protection in the workplace and the differentiation between mixtures and pure chemicals. • 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. • 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 glove may provide less resistance to the 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 selection of chemical resistant gloves. • Before usage, inspect the gloves for any defect or imperfections. • EN ISO 374-4:2019 Degradation levels 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. • Donning – Hold 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. • Where relevant, a list of the substances contained in the glove which are known to cause allergies, per listed in Annex G of EN ISO 21420:2020, shall be supplied on request. • Components used in glove manufacturing may cause allergic reactions in some users. If allergic reactions occur, seek for medical advice immediately. • In storage, avoid excessive heat. Open box should be shielded from exposure to direct sun or fluorescent lighting. Gloves are packed in dispenser which is suitable for transport. Keep the gloves in box when not in use.

Minimum Breakthrough Duration Time > 240min	Chemotherapy Drug & Concentration
	Cisplatin 1.0 mg/mL, Cyclophosphamide (Cytoxan) 20.0 mg/mL, Cytarabine 100 mg/mL, Doxorubicin (DTIC) 10.0 mg/mL, Doxorubicin Hydrochloride 2.0 mg/mL, Etoposide 20.0 mg/mL, Fluorouracil 50.0 mg/mL, Ifosfamide 50.0 mg/mL, Methotrexate 25.0 mg/mL, Mitomycin C0.5 mg/mL, Mitoxantrone 2.0 mg/mL, Paclitaxel (Taxol) 6.0 mg/mL, Vincristine Sulfate 1.0 mg/mL
	Fentanyl citrate and concentration
	Fentanyl citrate injection (100 mcg/2mL)

30.2min Thiotepa (10.0 mg/mL)
10.1min Carmustine (BCNU) (3.3 mg/mL)

Warning: Not recommended for use with Carmustine and Thiotepa.

Tested for use with Chemotherapy Drugs using ASTM D6978.

Resistance to Permeation by Chemicals	Level	Mean Degradation (%)
*4% Chlorhexidine Digluconate	6	19.0
40% Sodium Hydroxide (K)	6	-42.9
10-13% Sodium Hypochlorite	6	14.7
50% Sulphuric Acid	6	-20.5
5% Ethidium Bromide	6	-3.4
50% Glutaraldehyde	6	27.4
0.1% Phenol	6	33.8
1.5% Methanol in Water	6	21.9
3% Povidone-iodine	6	33.7
10% Sodium Percarbonate	6	15.4
10% Acetic Acid	4	66.7
37% Formaldehyde (T)	3	5.0
30% Hydrogen Peroxide (P)	2	22.8
65% Ammonium Hydroxide (O)	0	-52.0
65% Nitric Acid (M)	0	97.6
70% Isopropanol	0	62.2
35% Ethanol	0	38.8
99% Acetic Acid (N)	0	93.9

* Permeation rate 7µg/ cm²/min

Permeation Performance Level & Measured Breakthrough Time (minutes)
0 > * 1 > 10 min, 2 > 30 min, 3 > 60 min, 4 > 120 min, 5 > 240 min, 6 > 480 min

*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.



G-LF-XXXXXX-F-R0
Last update in 2022

FR POWDER FREE NITRILE EXAMINATION GLOVES • Non sterile • Single Use • Recommended for medical use

Règlement sur les dispositifs médicaux (UE) 2017/745 et règlement sur les équipements de protection individuelle (UE) 2016/425 (catégorie III). • Règlement sur les dispositifs médicaux de 2002 (SI 2002 No. 618, tel que modifié) (UK MDR 2002) • Organisme notifié de l'UE pour le (module B) et le module C2 est SATRA Technology Europe Limited (2777) • Organisme agréé au Royaume-Uni pour le (module B) et le module C2 est SATRA Technology Center Limited (AB0321) • La déclaration de conformité de l'UE et la déclaration de conformité du Royaume-Uni sont accessibles à l'adresse www.intouchcares.com. • Ces informations ne reflètent pas la durée réelle de la protection sur le lieu de travail et la différenciation entre les mélanges et les produits chimiques purs. • La résistance chimique a été évaluée dans des conditions de laboratoire à partir d'échantillons prélevés sur la paume uniquement (sauf dans les cas où le gant mesure 400 mm ou plus - où la manchette est également testée) et ne concerne que le produit chimique testé. Elle peut être différente si le produit chimique est utilisé dans un mélange. • Il est recommandé de vérifier que les gants sont adaptés à l'utilisation prévue car les conditions sur le lieu de travail peuvent différer de l'essai de type en fonction de la température, de la abrasion et de la dégradation. • Le gant est utilisé, le gant est dégradé, la dégradation peut offrir une moindre résistance au produit chimique dangereux en raison des modifications de ses propriétés physiques. Les mouvements, les accrochages, les frottements, la dégradation causée par le contact chimique, etc. peuvent réduire considérablement la durée d'utilisation réelle. Pour les produits chimiques corrosifs, la dégradation peut être le facteur le plus important à prendre en compte dans le choix de gants résistants aux produits chimiques. • Avant l'utilisation, inspectez les gants pour détecter tout défaut ou imperfection. • EN ISO 374-4:2019 Les niveaux de dégradation indiquent le changement de la résistance à la perforation des gants après exposition au produit chimique de référence. • La résistance à la pénétration a été évaluée dans des conditions de laboratoire et ne concerne que les spécimens testés. • Enfilage - Tenez le gant par le talon d'une main. Alignez le pouce du gant avec le pouce de l'autre main et glissez votre main dans le gant, un doigt dans chaque doigt du gant. Tirez sur la paume du gant pour obtenir un bon ajustement. Enfilez l'autre gant en suivant la même procédure. • Enlever le gant - Tenez le talon du gant et tirez vers le doigt jusqu'à ce que le gant se détache. • Le cas échéant, une liste des substances contenues dans le gant et connues pour provoquer des allergies, telles qu'énumérées à l'annexe G de la norme EN ISO 21420:2020, doit être fournie sur demande. • Les composants utilisés dans la fabrication des gants peuvent provoquer des réactions allergiques chez certains utilisateurs. En cas de réaction allergique, consultez immédiatement un médecin. • Lors du stockage, évitez toute chaleur excessive. La boîte ouverte doit être protégée de l'exposition directe au soleil ou à un éclairage fluorescent. Les gants sont emballés dans un distributeur qui convient au transport. Conservez les gants dans leur boîte lorsqu'ils ne sont pas utilisés.

Temps de détection minimal de la perçure > 240min	Médicament de chimiothérapie et concentration
	Cisplatine 1.0 mg/mL, Cyclophosphamide (Cytoxan) 20.0 mg/mL, Cytarabine 100 mg/mL, Doxorubicine (DTIC) 10.0 mg/mL, Doxorubicine Hydrochloride 2.0 mg/mL, Etoposide 20.0 mg/mL, Fluorouracil 50.0 mg/mL, Ifosfamide 50.0 mg/mL, Methotrexate 25.0 mg/mL, Mitomycine C0.5 mg/mL, Mitoxantrone 2.0 mg/mL, Paclitaxel (Taxol) 6.0 mg/mL, Sulfate de Vincristine 1.0 mg/mL
	Citrate de fentanyl et concentration
	Injection de citrate de fentanyl (100 mcg/2mL)

30.2min Thiotepa (10.0 mg/mL)
10.1min Carmustine (BCNU) (3.3 mg/mL).

Avertissement : Non recommandé pour une utilisation avec Carmustine et Thiotepa.

Testé pour une utilisation avec des médicaments de chimiothérapie selon ASTM D6978.

Résistance à la perméation par les produits chimiques	Niveau	Moyenne Dégradation (%)
*4% Digluconate de chlorhexidine	6	19.0
Hydroxyde de sodium à 40% (K)	6	-42.9
10-13% Hypochlorite de sodium	6	14.7
50% Acide sulfurique	6	-20.5
5% Bromure d'éthidium	6	-3.4
50% Glutaraldéhyde	6	27.4
0.1% Phénol	6	33.8
1.5% Méthanol dans l'eau	6	21.9
3% Povidone-iodée	6	33.7
10% Percarbonate de sodium	6	15.4
10% Acide acétique	4	66.7
37% Formaldéhyde (T)	3	5.0
30% Peroxyde d'hydrogène (P)	2	22.8
65% Ammonium Hydroxyde (O)	0	-52.0
65% Acide nitrique (M)	0	97.6
70% Isopropanol	0	62.2
35% Ethanol	0	38.8
99% Acide acétique à 99 % (N)	0	93.9

* Taux de perméation 7µg/ cm²/min

Niveau de performance de perméation et temps de percée mesurés (minutes)
0 > * 1 > 10 min, 2 > 30 min, 3 > 60 min, 4 > 120 min, 5 > 240 min, 6 > 480 min

*Indique que le gant est inférieur au niveau de performance minimum tel qu'indiqué dans la norme EN ISO 374-1:2016 +A1:2018 pour le risque individuel donné.

RO POWDER FREE NITRILE EXAMINATION GLOVES • Non sterile • Single Use • Recommended for medical use

Regulamentul privind Dispozitivele Medicale (UE) 2017/745 și Regulamentul privind Echipamentul Individual de Protecție (UE) 2016/425 (Categorie III) • Regulamentul privind Dispozitivele Medicale 2002 (SI 2002 Nr. 618, cu modificări) (UK MDR 2002) • Organismul Notificat UE pentru (Modulul B) și Modulul C2: SATRA Technology Europe Limited (2777) • Organismul Notificat MB pentru (Modulul B) și Modulul C2: SATRA Technology Center Limited (AB0321) • Declarația de Conformitate UE și Declarația de Conformitate MB sunt accesibile la adresa www.intouchcares.com • Informația dată nu se referă la protecția locului de muncă și siguranța la diferite amestecuri din produse chimice. • Rezistența chimică a fost evaluată în condiții de laborator, mostrele folosite au fost selectate doar din palmă, cu excepția cazurilor când mîna are 400 mm și mai mult - unde și manșeta este testată și se referă doar la substanța chimică testată. Rezultatele pot fi diferite dacă este folosit un amestec de substanțe chimice. • Se recomandă de a verifica dacă mînușile sunt potrivite pentru a fi folosite în scopul propus, deoarece condițiile locului de muncă pot fi diferite de tipul testărilor efectuate și se pot diferenția prin temperatură, abraziune și degradare. • Mînușile de protecție, în timpul utilizării, pot oferi o rezistență mai mică la substanțele chimice periculoase din cauza modificărilor proprietăților fizice la acțiunea acestor compuși chimici. Mișcarea, strângerea, frecarea, degradarea cauzată de interacțiunea chimică etc. poate reduce semnificativ timpul real de utilizare. Pentru produsele chimice corozive, degradarea poate fi cel mai important factor pentru a fi luat în considerare la selectarea mînușilor rezistente la produsele chimice. • Înainte de folosire, verificați mînușile la lipsa defectelor și imperfecțiunilor. • EN ISO 374-4:2019 Nivelele de degradare indică modificarea rezistenței mînușilor la perforare după expunerea la substanțele chimice. • Rezistența la penetrare a fost evaluată în baza condițiilor de laborator și se referă doar la speciile testate. • Îmbrăcarea - Apucați mînușa de margine cu o mînă. Introduceți degetul mare al mînușii pe degetul mare al celeilalte mîni și trageți mîna în mînușă, fiecare deget al mîinii în degetul mînușii. Trageți astfel mînușa încît să se potrivească. Îmbrăcați cealaltă mînușă după același scenariu. • Dezbrăcarea - Țineți marginea mînușii și trageți de pe degete pînă mînușa va ieși. • Unde e cazul, se va oferi la cerere lista componentelor mînușii care sunt recunoscute ca alergeni, menționate în Anexa G la EN ISO 21420:2020. • Componentele folosite la producerea mînușilor pot cauza reacții alergice la unii utilizatori. Dacă se produce o reacție alergică, adresăți-vă urgent medicului. • Mînușile se vor păstra la loc ferit de caldură în exces. Cutia deschisă se va proteja de expunerea directă la soare sau lumină fluorescentă. • Mînușile sunt ambalate în cutie care se potrivește pentru transportare. Păstrați mînușile în cutie atînci cînd nu sunt folosite.

Temp minim de detectare a perforării > 240min	Medicamente chimioterapice și concentrație
	Cisplatină 1.0 mg/mL, Ciclofosfamidă (Cytoxan) 20.0 mg/mL, Citarabină 100 mg/mL, Dacarbazină (DTIC) 10.0 mg/mL, Doksorubicină clorhidrat 2.0 mg/mL, Etoposid 20.0 mg/mL, Ifosf.0 mg/mL, Mitomicina C0.5 mg/mL, Metotrexat 25.0 mg/mL, Mitomicina C0.5 mg/mL, Mitoxantronă 2.0 mg/mL, Paclitaxel (Taxol) 6.0 mg/mL Sulfat de vincristină 1.0 mg/mL
	Citrat de fentanil și concentrație
	Injectie cu citrat de fentanil (100 mcg/2ml)

30.2min Thiotepa (10.0 mg/mL)
10.1min Carmustină (BCNU) (3.3 mg/mL).

Atenție: Nu se recomandă folosirea cu Carmustină și Thiotepa.

Testate la folosirea cu Medicamente chimioterapice folosind ASTM D6978.

Rezistența Permeabilității Produselor Chimice	Nivel	Degradare medie (%)
*4% Digluconat de clorhexidină	6	19.0
40% Hidroxid de sodiu (K)	6	-42.9
10-13% Hipoclorit de sodiu	6	14.7
50% Acid sulfuric	6	-20.5
5% Bromură de etidiu	6	-3.4
50% Glutaraldehidă	6	27.4
0.1% Fenol	6	33.8
1.5% Soluție apoasă de metanol	6	21.9
3% Iod-Povidonă	6	33.7
10% Percarbonat de sodiu	6	15.4
10% Acid acetic	4	66.7
37% Formaldehidă (T)	3	5.0
30% Peroxid de hidrogen (P)	2	22.8
25% Hidroxid de amoniu (O)	0	-52.0
65% Acid azotic (M)	0	97.6
70% Izopropanol	0	62.2
35% Etanol	0	38.8
99% Acid acetic (N)	0	93.9

* Rata permeabilității 7µg/ cm²/min

Nivel de Performanță la Permeabilități și Timpul Măsurat de Străpungere (minute)
0 > * 1 > 10 min, 2 > 30 min, 3 > 60 min, 4 > 120 min, 5 > 240 min, 6 > 480 min

*Indică faptul că mînușa este sub nivelul minim de performanță după cum se indică în EN ISO 374-1:2016 +A1:2018 pentru pericolul dat individual.

110mm



Available Size

XL

Last update in August 2022

- Non sterile • Single Use
- Recommended for medical use

Medical Device Regulation (EU) 2017/745 & Personal Protective Equipment Regulation (EU) 2016/425 (Category III) • Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002) • European Union (EU) 2018/1185 (EU Regulation 2018/1185) • European Union (EU) 2017/1372 (UK Approved Body for (Module B) and Module CZ: SATRA Technology Centre Limited (AB0321) • EU Declaration of Conformity & UK Declaration of Conformity is accessible

• The duration of protection in the workplace and the differentiation between mixtures and pure chemicals. • The chemical resistance has been assessed under laboratory conditions from samples taken from the test glove. • The chemical resistance is assessed for the test glove – where the cuff is tested also and relates only to the chemical tested. It can be different if the chemical used in a mixture. It is recommended to check that the gloves are suitable for the intended use because the chemical resistance is not affected by the use of the gloves in the workplace, temperature, abrasion and degradation. • When used, protective glove may provide less resistance to the dangerous chemical due to changes in physical properties. Movements, snagging, rubbing, degradation, etc. • The chemical resistance is not affected by the use of the gloves in the workplace. • Significantly. For corrosive chemicals, degradation can be the most important factor to consider in selection of chemical resistant gloves. • Before usage, inspect the gloves for any defect or imperfections. • EN 388:2016 is a standard for testing the resistance of gloves to mechanical 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. • Donning – Hold the glove by the wrist and pull it over the hand. • Aligned – Hold the glove by the wrist and slide your hand into the glove, one finger into each glove finger. Pull by the glove palm to get a good fit. Do not the other glove by the same procedure. • Doffing – Hold the glove, bend and pull toward the finger thumb side. • Hold the cuff of the glove. • When wearing gloves, avoid activities in the glove which are known to cause allergies, per listed in Annex C of EN ISO 21420:2020, shall be supplied on request. • Components used in glove manufacturing may cause allergic reactions in some users. If you are allergic to any of the components, do not use the gloves. • Storage, avoid excessive heat. Open box should be shielded from exposure to direct sun or fluorescent lighting. Gloves are packed in boxes, which is suitable for transport. Keep the gloves box white.

00110586

Resistance to Permeation by Chemicals	Level	Mean Degradation (%)
Diethylamine (G)	0	7.2
96% Sulphuric Acid (L)	0	100.0
40% Sodium Hydroxide (K)	6	-14.9
30% Hydrogen Peroxide (P)	2	-15.6
37% Formaldehyde (T)	1	-22.4

Permeation Performance Level & Measured Breakthrough Time
(minutes) 0 > *, 1 > 10 min, 2 > 30 min, 3 > 60 min, 4 > 120 min, 5 > 240
min, 6 > 480 min

*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.

50mm

- Non stérile • Usage unique
- Recommandés pour un usage médical

Le règlement des dispositifs médicaux (UE) 2017/745 réglemente les équipements de protection individuelle (UE) 2016/425 (catégorie III). Le règlement sur les dispositifs médicaux de 2002 (SI 2002 No. 618, tel que modifié) (UK MDR 2002) : L'organisme notifié pour la France est le Centre National de Surveillance des Produits de Santé Europe Limited (27777) : L'organisme agréé au Royaume-Uni pour le module B et le module CE sont SATRA Technology Center Limited et SATRA Technology Center Limited (UK) Ltd. Les données de conformité du Royaume-Uni sont accessibles à l'adresse www.intouchcare.com. • Ces informations ne reflètent pas la durée réelle de la protection sur le lieu de travail et la détermination entre la durée de la protection et la durée de la protection chimique a été évaluée dans des conditions de laboratoire à partir d'échantillons prélevés sur la paume uniquement (sauf dans les cas de tests de la peau). • Les tests de la peau ont été effectués sur la peau testée et ne concernent que le produit chimique testé. Elle peut être différente si le produit chimique est utilisé dans un mélange. • Il est prévu que les conditions sur le lieu de travail peuvent différer de l'essai de test en fonction de la température, de l'abrasion et de la dégradation. • Lorsqu'il est utilisé, le gant de protection peut offrir une protection contre les produits chimiques, mais ne protège pas des modifications de ses propriétés physiques. Les mouvements, les accrochages, les frottements, la dégradation causée par le produit chimique, la dégradation causée par l'abrasion, la dégradation par l'abrasion. Pour les produits chimiques corrosifs, la dégradation peut être le facteur le plus important à prendre en compte dans le choix de gants résistants aux produits chimiques. • Les gants de protection ne protègent pas contre les produits chimiques, l'imperfection. • EN ISO 374-4:2019 Les niveaux de dégradation indiquent le changement de la résistance à la perforation des gants en fonction de la dégradation. • Les gants de protection ne protègent pas la pénétration a été évaluée dans des conditions de laboratoire et ne concerne que les spécimens testés. • Enfilez - Tenez le gant par le talon d'une main. Alignez le pouce du gant avec le pouce de l'autre main. • Retirez le gant en tirant sur le gant par le talon d'une main. Tirez sur la paume du gant pour obtenir un bon ajustement. • Enfilez l'autre gant en suivant la même procédure. • Enlever le gant - Retirez le gant en tirant sur le gant par le talon d'une main. • Le gant se détache. Le cas échéant, une liste des substances contenues dans le gant et connues pour provoquer des allergies, telles qu'énumérées à l'annexe 2 de la norme EN ISO 374-4:2019, doit être fournie. Les gants peuvent provoquer des réactions allergiques chez certains utilisateurs. En cas de réaction allergique, consulter immédiatement un médecin. • Les gants de protection ne protègent pas la peau ouverte doit être protégée de l'exposition directe au soleil ou à un éclairage fluorescent. Les gants sont emballés dans un emballage opaque et doivent être conservés. Les gants dans un emballage transparent ne sont pas utilisables.

Résistance à la perméation par les produits chimiques	Niveau	Moyenne Dégradation (%)
Diéthylamine (G)	0	7.2
96% Acide sulfurique (L)	0	100.0
40% Hydroxyde de sodium (K)	6	-14.9
30% Peroxyde d'hydrogène (P)	2	-15.6
37% Formaldéhyde (T)	1	-22.4

Niveau de performance de perméation et temps de percée mesuré (minutes)
0 > * 1 > 10 min. 2 > 30 min. 3 > 60 min. 4 > 120 min. 5 > 240 min. 6 > 480 min

*Indique que le gant est inférieur au niveau de performance minimum tel qu'indiqué dans la norme EN ISO 374-1:2016 +A1:2018 pour le risque individuel donné

- Nesterile • De unică folosință
- Recomandate a fi folosite în scop medical

[illegible]

Rezistența Permeabilității Produselor Chimice	Nivel	Degradare medie (%)
Dietilamină (G)	0	7.2
96% Acid sulfuric (L)	0	100.0
40% Hidroxid de sodiu (K)	6	-14.9
30% Peroxid de hidrogen (P)	2	-15.6
37% Formaldehidă (T)	1	-22.4

Nivel de Performanță al Permeabilității și Timpul Măsurat de Străpungere (minute) 0 > *, 1 > 10 min, 2 > 30 min, 3 > 60 min, 4 > 120 min, 5 > 240 min, 6 > 480 min

*Indică faptul că mănușa este sub nivelul minim de performanță după cum se indică în EN ISO 374-1:2016 +A1:2018 pentru pericolul dat individual

Customer details: Kossan International Sdn Bhd
Wisma Kossan, Lot 782
Jalan Sungai Putus, Off Batu 3 3/4
Jalan Kapar
42100 Klang
Selangor Darul Ehsan
Malaysia

SATRA reference: SPC0272832 /1827

Your reference:

Date of report: 18 July 2018

Samples received: 4 July 2018

For the attention of: Cho Sow Fong

Date(s) work carried out: 16 July 2018

TECHNICAL REPORT

Subject: Testing of gloves identified as Powder Free Latex gloves non-sterile (PF NR) in accordance with EN 388: 2016 clause 6.1 Abrasion resistance, EN 374-2: 2014 and EN 420: 2003 + A1: 2009 clauses 5.1 length and fit and 5.2 dexterity

Conditions of Issue:

This report may be forwarded to other parties provided that it is not changed in any way. It must not be published, for example by including it in advertisements, without the prior, written permission of SATRA.

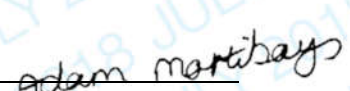
Results given in this report refer only to the samples submitted for analysis and tested by SATRA. Comments are for guidance only.

Tests marked $\neq$ fall outside the UKAS Accreditation Schedule for SATRA. All interpretations of results of such tests and the comments based upon them are outside the scope of UKAS accreditation and are based on current SATRA knowledge.

A satisfactory test report in no way implies that the product tested is approved by SATRA and no warranty is given as to the performance of the product tested. SATRA shall not be liable for any subsequent loss or damage incurred by the client as a result of information supplied in the report.

The uncertainty of the results (UoM) in this report is based on a standard uncertainty multiplied by a coverage factor $k=2$, which provides for a confidence level of approximately 95%.

Report signed by: Adam Mortiboys
Position: PPE Technologist
Department: Safety Product Testing



Work Requested

Samples of gloves, see Table 1, were received by SATRA, for testing in accordance with EN 388:2016 Protective gloves against mechanical risks, clause 6.1 Abrasion resistance only, EN 420:2003+A1:2009. Protective gloves. General requirements and test methods, Clauses 5.1 length and fit and 5.2 dexterity, and EN 374-2:2014. Protective gloves against dangerous chemicals and microorganisms. Determination of resistance to penetration.

Table 1 – Samples Received

Sample description as stated by the client	Sizes submitted for testing	Colour of samples submitted	Approximate weight of one glove
Powder Free Latex gloves non-sterile (PF NR)	6 – 10	Cream	Size: 6 Weight: 4.4g



Powder Free Latex gloves non-sterile (PF NR)

Conclusion

Standard	Clause / Property		Result
EN 420: 2003 + A1: 2009	5.1	Length and fit	See note ■
	5.2	Dexterity	Level 5
EN 388:2016	6.1	Abrasion resistance	Level 0
EN 374-2: 2014	7.2	Air leak	See note ●
	7.3	Water leak	Pass

Note ■ – Where gloves do not meet the minimum length requirements specified in Table 1 of EN 420:2003 + A1:2009, the standard therefore requires that the manufacturer shall clearly state in the user instructions the intended application of the gloves and the reason why the gloves do not conform to the minimum length requirements.

Note ● – As per clause 4.3 of EN 374-2:2014, the gloves submitted for testing were found to be unsuitable for the Air leak test. Therefore as per EN 374-2 only the Water leak test has been performed.

Testing

Samples for testing were conditioned for at least 24 hours in a conditioned environment maintained at $(23 \pm 2) ^\circ\text{C}$ and $(50 \pm 5) \%$ relative humidity. Testing was carried out within the same environment.

Requirements

Table 2 – Requirements for EN 420:2003 + A1:2009 Clause 5 Size and Dexterity

Glove size	6	7	8	9	10	11
Minimum length / mm	220	230	240	250	260	270

Performance level	1	2	3	4	5
Diameter of dexterity pin /mm	11.0	9.5	8.0	6.5	5.0

Table 3 – Requirements for EN 388:2016 Levels of performance

Performance Level	1	2	3	4	5
6.1 Abrasion resistance (number of rubs)	100	500	2000	8000	-

Table 4 - Requirements for EN 374-2: 2014

7.2 Air leak test	No leak to be detected
7.3 Water leak test	No leak to be detected

Test Results

Table 5 - EN 420:2003 + A1:2009 Test Results for gloves identified as Powder Free Latex gloves non-sterile (PF NR)

Clause / Test	Test Results		UoM	Result
5.1 Glove length, comfort and fit	Size	Length /mm		
	6	Left 246 Right 251		
	Comments on fit: Satisfactory			
	7	246 249	± 0.3 mm	See note ■
	Comments on fit: Satisfactory			
	8	249 250		
	Comments on fit: Satisfactory			
9	246 247			
	Comments on fit: Satisfactory			
5.2 Dexterity	Size	Minimum pin diameter / mm		
	6	5.0	N/A	Level 5
	7	5.0		
	8	5.0		
	9	5.0		
	10	5.0		

Table 6 - EN 388:2016 Test Results of gloves identified as Powder Free Latex gloves non-sterile (PF NR)

Clause / Test	Test Results			UoM	Level
6.1 Abrasion resistance	Sample	Failure between / cycles	Physical change observed at end point		
	1	<100	Holed		
	2	<100	Holed		
	3	<100	Holed		
	4	<100	Holed		
	Abradant-Klingspor PL31B Gritt 180 Tape-3M 465 Abrasion machine compliant with EN 388:1994 Clause 6.1.3				
				± 5 % See note ♣	0

Table 7 - EN 374-2:2014 Test Results of gloves identified as Powder Free Latex gloves non-sterile (PF NR)

Clause / Test	Test Results		UoM	Result
7.2 Air leak test	Total Air Pressure Used	2.51 kPa	± 2.8 mmH ₂ O	See note •
	Sample size	Leaks		
	6			
	7			
	8	See note •		
	9			
7.3 Water leak test	10		N/A	Pass
	Sample size	Leaks		
	6	No leaks detected		
	7	No leaks detected		
	8	No leaks detected		
	9	No leaks detected		
	10	No leaks detected		

Additional Information / Notes

Note • – Estimated uncertainty of measurement applied at point of test (e.g. to applied force or to tolerance limits) to ensure product meets requirements of the standard

TERMS AND CONDITIONS FOR THE SALE OF GOODS AND/OR THE PROVISION OF SERVICES

1. GENERAL

- 1.1 Work done, Services undertaken or the sale of Goods are subject to the terms and conditions detailed below and (subject to clause 5.2) all other conditions, warranties and representations, expressed or implied by statute relating thereto are hereby excluded.
- 1.2 SATRA Technology Centre Limited, its subsidiaries and associated companies (hereinafter referred to as "SATRA") may perform Services for or supply Goods to persons or entities (public, private or governmental) issuing instructions (hereinafter termed the "Client"). Each also known individually as a Party, or jointly as Parties.
- 1.3 These terms and conditions will apply to the Contract between SATRA and the Client to the exclusion of any other terms which the Client may seek to impose or which may be implied by trade, custom, practice or course of dealing
- 1.4 Unless otherwise agreed in writing no party other than the Client is entitled to provide instructions or information relating to the Goods or Services required or to the delivery of goods, results, reports or certificates.
- 1.5 All references in these terms and conditions to:
 - (a) the "Contract" is the contract between SATRA and the Client for the supply of Goods or Services which is made subject to these terms and conditions; and
 - (b) "Services" are the work or services to be supplied or performed under the Contract (including where relevant the supply of software, components and consumables); and
 - (c) "Goods" are the equipment, consumables or other physical items sold under the Contract (including documents, drawings or other information required in order to operate the equipment).
- 1.6 All drawings, descriptive matter, specifications and advertising material (including brochures and catalogues) are issued or published with the sole purpose of giving an indication of the goods or services being described and shall not form part of the Contract.
- 1.7 Where SATRA and the Client agree that the sale of Goods shall be governed by Incoterms 2010 (or any subsequent revision thereto) then the sale shall be governed by the relevant Incoterms mode of transport which is agreed by SATRA and the Client.

2. FEES AND PAYMENT

- 2.1 Where SATRA has agreed to perform the Services or supply the Goods on the basis of credit then payment terms are net 21 days from date of invoice, unless otherwise specified and may require part payment prior to delivery of the Services or Goods. In the event of the Client failing to make payment as agreed SATRA will be entitled to withhold delivery of the Goods or Services or cancel the Contract. SATRA reserves the right to charge interest on any overdue payments at a rate of 1.5% per month accruing on a daily basis from the date the invoice is due until the date payment is received.
- 2.2 Where the provision of Services or the sale of Goods is subject to a proforma invoice then SATRA shall not be obliged to start working on the provision of the Goods or Services until after payment in full has been made as cleared funds to SATRA.
- 2.3 SATRA reserves the right to charge for any and all expenses incurred as a result of performing the Services required by the Client. Although SATRA will try and provide an estimate of such expenses these may change as a result of circumstances out of SATRA's control.
- 2.4 Unless otherwise agreed in writing, the price for the Goods or Services shall be the price set in the order acknowledgement. SATRA shall not be bound by any price quoted which is not in writing. Prices for the sale of Goods include packing cases and materials but not carriage or installation which will be quoted separately and as agreed with the Client.
- 2.5 Quotations are valid from the date of issue for a period of 90 days unless otherwise specified or agreed in writing.
- 2.6 Should the Client become insolvent, bankrupt, subject to an administration order, enter into liquidation or receivership, or make arrangements with creditors SATRA reserves the right to cancel the Contract and terminate the supply of the Goods or Services. Where the Contract with SATRA is terminated all outstanding monies due from the Client to SATRA shall be immediately payable, and any materials supplied by SATRA to the Client returned. Termination of the Contract shall be without prejudice to any of SATRA's accrued rights.
- 2.7 All invoices issued by SATRA are payable in full. The Client is responsible for payment of withholding and any other taxes and all import duties. Payments made to SATRA shall not be reduced by such amounts.
- 2.8 The Client shall not be entitled to withhold or defer payment due to SATRA as a result of any dispute or counter claim that it may allege against SATRA.
- 2.9 SATRA reserves the right to bring action against the Client in order to collect unpaid fees, including court action. All fees associated with such actions shall be paid for by the Client including legal fees and related costs.
- 2.10 Where unforeseen costs arise as a result of provision of the Goods or carrying out the Services SATRA shall inform the Client immediately but reserves the right to charge additional costs to cover said costs and expenses.

3. INTELLECTUAL PROPERTY RIGHTS

- 3.1 All intellectual property rights belonging to a Party prior to entry into the Contract shall remain with that Party. Nothing in this Contract shall allow transfer of any intellectual property rights from one Party to the other.
- 3.2 In the event of certification services the use of certification marks by the Client may be subject to national and international laws and regulations. The responsibility for the use of these certification marks lies solely with the Client.
- 3.3 All intellectual property rights in reports, drawings, graphs, charts, photographs or any other material (in whatever medium) produced by SATRA pursuant to this Contract shall belong to SATRA. The Client shall have the right to use said material in accordance with the terms of this Contract.
- 3.4 The Client agrees and acknowledges that SATRA retains any and all propriety rights in concepts, ideas and inventions that may arise during the preparation or provision of any report (including any deliverables provided by SATRA to the Client) and the provision of the Services to the Client.
- 3.5 All intellectual property rights in any software supplied to the Client shall belong to SATRA or SATRA's licensors. With respect to the sale of SATRA Timeline, SATRASUMM and SATRA Visionstitch, provided that the Client is a member of SATRA and has paid its annual Smartcare fee then the Client will be entitled to use the software for its own internal use and will be entitled to receive minor software upgrades and fixes. SATRA may however terminate the supply of software upgrades and fixes for older versions of software which it no longer considers viable to support. The Client's rights to use the software and receive software upgrades and fixes will terminate if the Client has not paid its annual Smartcare fee. Major upgrades are not included within the entitlement to upgrades but may be offered by SATRA from time to time for an additional fee.
- 3.6 SATRA shall observe all statutory provisions with regard to data protection including but not limited to the provisions of the Data Protection Act 1998. To the extent that SATRA processes or gets access to personal data in connection with the Services or otherwise in connection with this Contract, it shall take all reasonable technical and organisational measures to ensure the security of such data (and guard against unauthorised or unlawful processing, accidental loss, destruction or damage to such data).

4. SUSPENSION OR TERMINATION OF SERVICES

- 4.1 Cancellation by the Client of orders for Goods or Services will only be acceptable by prior agreement with SATRA and a charge will usually be made.
- 4.2 SATRA shall not be liable for any delay or failure in providing the Goods or Services due to circumstances beyond its reasonable control (including any failure by the Client to comply with its obligations). If any such circumstances arise which prevent SATRA from delivering the Goods or completing the Services, then SATRA will be entitled to cancel or reschedule the delivery of Goods or Services at its discretion. In the event of cancellation SATRA will be entitled to retain all fees paid by the Client for Goods or Services already supplied but will refund to the Client any fees paid by the Client for Goods or Services which have not yet been supplied. The Client will not be liable for any non-refundable expenses already incurred by SATRA in relation to Goods or Services not yet supplied unless the cancellation is due to the Client's failure to comply with its obligations under the Contract.

5. LIABILITY AND INDEMNIFICATION

- 5.1 Reports are issued on the basis of information, documents and/or samples submitted to SATRA by the Client, or on behalf of the Client and are provided solely for the benefit of the Client who is responsible for acting as it sees fit on the basis of such reports and findings. Subject to clause 5.2, neither SATRA nor any of its employees, agents or subcontractors shall be liable to the Client or any third party for any actions taken or not taken on the basis of such findings and reports, nor for any incorrect results arising as a result of unclear, erroneous, incomplete, misleading or false information provided to SATRA.
- 5.2 Nothing in these terms and conditions shall limit or exclude SATRA's liability for:
 - (a) death or personal injury caused by its negligence or the negligence of its employees or agents;
 - (b) fraud or fraudulent misrepresentation;
 - (c) breach of the terms implied by Section 12 of the Sale of Goods Act 1979;
 - (d) defective products under the Consumer Protection Act 1987; or
 - (e) any other liability which cannot be limited or excluded by applicable law.
- 5.3 Subject to clause 5.2 SATRA shall not be liable to the Client whether in contract, tort (including negligence), breach of statutory duty or otherwise arising under or in connection with the Contract for loss of profits, sales, contracts, anticipated savings, loss or damage to goodwill or any indirect or consequential loss.
- 5.4 Subject to clause 5.2 SATRA's total aggregate liability to the Client, whether in contract, tort (including negligence), breach of statutory duty or otherwise arising under or in connection with the Contract shall be limited to the total amount of fees for the Services or the price of the Goods (excluding any value added tax or other sales tax or expenses) payable by the Client to SATRA under the Contract or £100,000 whichever is the lower figure.

6. MISCELLANEOUS

- 6.1 If any one or more provisions of these conditions are found to be illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired thereby.
- 6.2 During the course of providing the Goods or Services and for a period of one year thereafter the Client shall not directly or indirectly entice, encourage or make any offer to SATRA's employees to leave their employment with SATRA.
- 6.3 The use of SATRA's corporate name or registered marks for advertising purposes is not permitted without SATRA's prior written authorisation.
- 6.4 All reports and documentation which are supplied to the Client under the Contract remain the property of SATRA until paid in full. Under no circumstances will a Client's purchase order override SATRA's retention of title in accordance with this clause.
- 6.5 The Client acknowledges that in entering into this Contract it has not relied on any representation, warranty, collateral contract or other assurance (except those set out or referred to in these terms and conditions) made by or on behalf of SATRA or any other party before entering into the Contract. The Client waives all rights and remedies that, but for this clause, might otherwise be available to it in respect of any such representation, warranty, collateral contract or other assurance.
- 6.6 All provisions of the Contract that limit or exclude the liability of SATRA are intended also to be for the benefit of SATRA's holding company (called SATRA, and being a company limited by guarantee and incorporated in England and Wales with company number 00153475), and shall accordingly be enforceable by such holding company as well as or instead of by SATRA, and on the basis that any limit on the liability of SATRA shall apply to it and to such holding company in the aggregate.

7. CONFIDENTIALITY

- 7.1 Unless specifically excluded in the terms of an individual contract between SATRA and the Client, the following shall apply to all deliverables including, reports, advice, drawings, photographs, specifications, data or other forms of media.
- 7.2 Deliverables referred to in clause 7.1 shall not be disclosed to third parties or used in litigation without the consent of SATRA.
- 7.3 Where SATRA has given consent to disclosure of any service deliverables referred to in clause 7.1, the Client shall draw the attention of the third party to these terms of business and the basis on which SATRA undertakes testing, reporting and advising. The Client shall indemnify SATRA for any failure to do so.
- 7.4 The service deliverables referred to in clause 7.1 are submitted to the Client as confidential documents. Confidentiality shall continue to apply after completion of the business, but shall cease to apply to information or knowledge which has come into the public domain through no breach of this Contract by the Client.
- 7.5 The Client shall not disassemble, remove parts or carry out any form of analysis on goods or materials sold by SATRA for the purposes of reverse engineering or obtaining information on the construction, content or composition of the item without the consent of SATRA.

8. AMENDMENT

- 8.1 No amendment to this Contract shall be effective unless it is in writing, expressly stated to amend this Contract and signed by an authorised signatory of both Parties.

9. DISPUTE RESOLUTION

- 9.1 If there should be a dispute between the parties to this Agreement they undertake to act with goodwill and to use all reasonable endeavours to resolve that dispute.
- 9.2 Failure to resolve any dispute by discussions between the parties shall, in the first instance, be referred to a mediator for resolution. The parties shall attempt to agree upon the appointment of a mediator, upon receipt, by either of them, of a written notice to concur in such appointment. Should the parties fail to agree within 21 days, either party, upon giving written notice, may apply to the President or the Vice President, for the time being, of the Chartered Institute of Arbitrators, for the appointment of a mediator.
- 9.3 Should the mediation fail, in whole or in part, either party may, upon giving written notice, and within twenty-eight days thereof, apply to the President or the Vice President, for the time being, of the Chartered Institute of Arbitrators, for the appointment of a single arbitrator, for final resolution. The arbitrator shall have no connection with the mediator or the mediation proceedings, unless both parties have consented in writing. The arbitration shall be governed by both the Arbitration Act 1996 and the Controlled Cost Rules of the Chartered Institute of Arbitrators (2000 Edition), or any amendments thereof, which Rules are deemed to be incorporated by reference into this clause. The seat of the arbitration shall be England and Wales.

TERMS AND CONDITIONS FOR THE SALE OF GOODS AND/OR THE PROVISION OF SERVICES

- 9.4 The laws of England shall govern the interpretation of this Contract. Subject to clauses 9.1, 9.2 and 9.3 any dispute arising out of or in connection with the Contract shall be subject to the exclusive jurisdiction of the courts of England. However, the Party obtaining a judgement in such courts shall be entitled to enforce it in any court it chooses.
- 10. PROVISION OF SERVICES**
- 10.1 SATRA shall provide Services using reasonable care and skill and in accordance with the Clients specific instructions and as confirmed by SATRA as part of the Contract review process.
- 10.2 Estimates for completion of the Services are made in good faith and date from receipt of a written order, payment of a proforma invoice if required, full information and samples to enable SATRA to proceed. While SATRA will make every effort to fulfil them, such estimates are subject to unforeseen events and if not achieved, cannot give rise to any claim. Time will not be of the essence in relation to the performance of the Services.
- 10.3 Results given in test reports or certificates refer only to samples submitted for analysis to SATRA. A satisfactory test report in no way implies that the product tested is approved by SATRA and no warranty is given as to the performance of the product tested.
- 10.4 SATRA may delegate all or part of the Services to a subcontractor and the Client authorises SATRA to disclose all information required to undertake the Services.
- 10.5 Where the Client requests SATRA to witness testing of other services being undertaken by a third party the Client agrees that SATRA's sole responsibility is to be present at the time of the work and to forward the results or confirm that the service has been undertaken. The Client agrees that unless otherwise agreed SATRA is not responsible for the condition or calibration of any equipment unless provided by SATRA.
- 10.6 Unless otherwise agreed in advance, test samples will be retained for 6 weeks from the date of the final report after which time they will be disposed of and SATRA shall cease to have any responsibility for such samples.
- Where the nature of the samples or the Services undertaken results in specialist disposal then SATRA reserves the right to pass the cost of such disposal onto the Client. Storage for longer periods may be possible only if agreed in advance and may incur a storage charge payable by the Client.
- Where practical and agreed in advance, samples may be returned at the Client's expense. However, samples are in most instances partially or fully destroyed as part of the work undertaken and SATRA cannot guarantee that samples will be returned in an "as new" condition.
- 10.7 Where SATRA receives documents reflecting engagements between the Client and third parties or documents belonging to third parties, such documents shall be considered as being for information only and shall not release the Client from any or all obligations to SATRA.
- 10.8 SATRA reserves the right to make changes to the Services, provided that such changes do not materially affect the nature or quality of the provision of these Services or where they are necessary in order to ensure that any applicable laws or safety requirements are complied with.
- 10.9 The Client acknowledges that SATRA by providing the Services, neither takes the place of the Client or any third party or releases them from any of their obligations.
- 11. CLIENT RESPONSIBILITIES RELATING TO THE PROVISION OF SERVICES**
- 11.1 The Client shall provide sufficient samples, information, instructions and documents as required to enable SATRA to carry out the Services in accordance with the methods, standards or other specifications as agreed.
- 11.2 Where applicable the Client shall allow access by members of SATRA staff to such premises where the Services are to be performed and provide any specialist equipment and personnel.
- 11.3 The Client shall inform SATRA in advance of any known hazards, dangers or other safety matters relating to samples submitted to SATRA or on site visits made by SATRA.
- 11.4 Where the Client fails to comply with any of its responsibilities SATRA reserves the right to suspend any Services until such time as the Client has complied and may require the Client to reimburse SATRA the amount of any additional costs arising from the suspension.
- 12. DELIVERY AND NON-DELIVERY OF GOODS**
- 12.1 Delivery dates for the supply of the Goods are approximate only and not guaranteed. Time of delivery is not of the essence of the Contract and SATRA shall not be liable for any delay in delivery of Goods.
- 12.2 Should expedited delivery be requested and agreed, SATRA shall be entitled to make additional charges to cover overtime or any other additional costs.
- 12.3 Delivery of the Goods shall take place at such location as SATRA and the Client agree. If the Client agrees to collect the Goods from SATRA's premises, then delivery will take place at those premises in which case the consignment of Goods as recorded by SATRA upon dispatch shall be evidence of the Goods received by the Client unless the Client can provide conclusive evidence to the contrary.
- 12.4 SATRA shall not be liable for the non-delivery of Goods (even if caused by SATRA) unless the Client provides written notice of non-delivery in accordance with clause 13.2. Liability for non-delivery of Goods shall in any event be limited to replacing the Goods within a reasonable time frame or the issue of a credit note to the value of the Goods not delivered.
- 12.5 Should delivery of the Goods be suspended or delayed by the Client for any reason SATRA reserves the right to charge for storage and for all expenses incurred, including loss of or wastage of resources that cannot otherwise be used. If the delay extends beyond 30 days SATRA shall be entitled to immediate payment for any Goods that are ready for delivery, and any other additional costs.
- 12.6 If for any reason the Client fails to accept delivery of any of the Goods when they are ready for delivery, or SATRA is unable to deliver the Goods on time because the Client has not provided appropriate instructions, documents, licenses or authorisations then risk in the Goods shall pass to the Client, the Goods and/or Services shall be deemed to have been delivered; and SATRA may store the Goods until delivery, whereupon the Client shall be liable for all related costs and expenses (including, without limitation, storage and insurance).
- 13. RISK/TITLE OF GOODS**
- 13.1 Subject to clause 12.6 the risk in the Goods will transfer to the Client on delivery of the Goods unless SATRA and the Client have agreed that the sale of the Goods will be governed by Incoterms 2010 (or any subsequent revision thereto) in which case risk will transfer to the Client in accordance with the Incoterms mode of transport which is agreed by SATRA and the Client.
- 13.2 The Company shall not accept responsibility for loss or damage in transit unless:
- In the case of sales where delivery of Goods is made in the United Kingdom SATRA is notified by the Client within 10 days of the invoice date of non-arrival of Goods and within 3 days of the invoice date of receipt of Goods damaged in transit; or
 - In all other cases the Client notifies SATRA on the non-arrival or damage in transit within a reasonable period of time as determined by SATRA.
- 13.3 Title to the Goods shall not pass to the Client until the earlier of when: -
- SATRA receives payment in full (in cash or cleared funds) for the Goods and any other Goods that SATRA has supplied to the Client in which case title to the Goods shall pass at the time of payment of all such sums; and
 - the Client resells the Goods in accordance with clause 13.5 in which case title shall pass to the Client immediately before the time at which the resale by the Client occurs.
- 13.4 Until ownership of Goods has passed to the Client, the Client shall:
- hold the Goods as SATRA's bailee;
 - store the Goods (at no cost to SATRA) separately from all other goods belonging to the Client or any third party in such a way that they remain readily identifiable as SATRA's property (including where the Goods have been sold to a 3rd party);
 - not destroy, deface or obscure any identifying mark or packaging on or relating to the Goods; and
 - maintain the Goods in satisfactory condition and keep them insured on SATRA's behalf for their full price against all risks to the reasonable satisfaction of SATRA. The Client shall obtain an endorsement of SATRA's interest in the goods on its insurance policy. On request the Client shall allow SATRA to inspect such Goods and shall produce the policy of insurance.
- 13.5 The Client may resell the Goods before ownership has passed to it solely on condition that sale shall be effected in the ordinary course of the Client's business at full market value.
- 13.6 If before title to the Goods passes to the Client, the Client becomes subject to any of the events referred to in clause 2.6 then without limiting any other right or remedy SATRA may have:
- the Client's right to resell the Goods or use them in the ordinary course of its business ceases immediately; and
 - SATRA may at any time require the Client to deliver up all Goods in its possession that have not been resold or irrevocably incorporated into another product; and
 - if the Client fails to do so promptly SATRA may exercise its rights under clause 13.7.
- 13.7 The Client grants SATRA, its agents and employees an irrevocable licence at any time to enter any premises where the Goods are or may be stored in order to inspect them, or, where the Client's right to possession has terminated, to recover them.
- 13.8 On termination of the Contract, howsoever caused, SATRA's (but not the Client's) rights contained in this clause 13 shall remain in effect.
- 14. PATENTS**
- 14.1 SATRA gives no indemnity against any claim of infringement of Letters Patent, Registered Design, Trade Mark or Copyright by the use of or sale of any article or material supplied to the Client. If its use is impossible without infringement of Letters Patent, Registered Design, Trade Mark or Copyright published at the date of the contract, SATRA will refund to the Client the purchase price of the said article or material provided that it is returned to SATRA free of charge. The Client warrants that any design or instruction furnished or given by the Client shall not be such as will cause SATRA to infringe any Letters Patent, Registered Design, Trade Mark or Copyright in the execution of the Client's order.
- 15. WARRANTY OF GOODS**
- 15.1 SATRA warrants that on delivery and for a period of 12 months from the date of delivery or within the shelf life of the Goods (whichever is the shorter period) the Goods shall be free from defects in design, material and workmanship.
- 16. DEFECTIVE GOODS**
- 16.1 Subject to clauses 16.6 and 16.7 if:
- the Client gives notice in writing to SATRA in accordance with clause 16.3 and during the period referred to in clause 15.1 that the Goods do not comply with the warranty in that clause; and
 - SATRA is given a reasonable opportunity of examining such Goods; and
 - the Client (if asked to do so by SATRA) returns such Goods to SATRA's place of business then SATRA will, at its option, repair or replace the defective Goods or refund the price of the defective Goods in full. SATRA reserves the right to repair the Goods at the Client's premises.
- 16.2 The Client must inspect all Goods upon delivery. Failure to do so may result in further charges being applied in the event of a return.
- 16.3 If Goods are found to be faulty, defective or damaged the Client must inform SATRA in writing as soon as reasonably possible and in any event within 10 working days of the fault, damage or defect being discovered.
- 16.4 Without prejudice to clause 16.1 if no notice of rejection has been received by SATRA within 3 months of delivery, the Client shall be deemed to have accepted the Goods.
- 16.5 SATRA will pay the reasonable costs of carriage, packaging and insurance for any defective Goods which are returned by the Client provided that SATRA is liable under clause 16.1 to repair or replace the defective Goods. If SATRA determines that the Goods are not defective or if SATRA is not liable to repair or replace the Goods due to the circumstances under clauses 16.6 or 16.7 then the Client will be responsible for the payment of such costs.
- 16.6 SATRA shall not be under any liability to repair or at its option replace or pay for the repair or replacement of any Goods which are found to be defective if:
- the defect is caused or substantially caused by wear and tear, overloading, misuse, neglect, modification or attempted modification carried out by any organisation other than by SATRA or their approved agents, or use with ancillary equipment not approved in writing by SATRA, or default in proper maintenance or cleaning; or
 - the Client authorises or carries out any repair or replacement of any Goods without first affording SATRA a reasonable opportunity to replace or repair them; or
 - the Client has breached any of the terms of the Contract under which the Goods were supplied; or
 - the Goods have been manufactured to a design or specification or in compliance with other information provided by the Client and the defect has arisen as a result of that design, specification or information;
- 16.7 Where Goods or parts of Goods are not manufactured by SATRA then SATRA shall be liable for defects only to the extent that SATRA obtains redress from the manufacturer or supplier thereof provided that:
- SATRA shall not be obliged to take any step to attempt to obtain such redress except at the request and expense of the Client and upon provision by the Client of a full indemnity as to costs for which SATRA may thereby become liable;
 - nothing in this condition 16.7 shall have effect as to impose upon SATRA any additional liability or obligations other than those referred to in condition 16.1.
- 16.8 Except as provided in clause 16.1 SATRA shall have no liability to the Client arising from any failure of the Goods to comply with the warranty in clause 15.1.

Terms and conditions – December 2016

Digitally signed by Dicusar Vladimir
Date: 2022.09.21 17:19:41 EEST
Reason: MoldSign Signature
Location: Moldova



• Powder-free Examination Gloves
• Nitrile
• Shield-aid
• Chemical permeation tested • Viral penetration tested • Fentanyl tested
• Chemotherapy drugs tested

XS
5 - 6
100 gloves
by weight

NITRILE
Shield-aid
Powder-free Examination Gloves

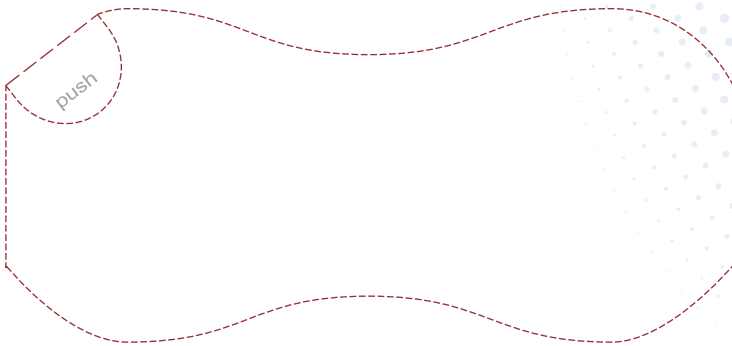
BLUE
XS
5 - 6
100 gloves
by weight

NITRILE

CS30

Shield-aid

Powder-free Examination Gloves



Recommended
for medical use



BLUE
XS
5 - 6
100 gloves
by weight

intouch™

XS
5 - 6
100 gloves
by weight

NITRILE LD
Shield-aid
Powder-free Examination Gloves

XS

NITRILE

Shield-aid

Powder-free Examination Gloves

- Gants d'examen nitrile sans poudre
- Puderfrei untersuchun gshandschuhe aus nitril
- Mănuși nitril nepudrate pentru examinare

XS
5 - 6
100 gloves
by weight

XS

NITRILE

Shield-aid

Powder-free Examination Gloves

In compliance with Medical Device Regulation (EU) 2017/745 & Personal Protective Equipment Regulation (EU) 2016/425 (Category III). Notified Body responsible for PPE EU Type Examination (Module B) and Module C2 On-going Conformity Assessment is SATRA Technology Europe Limited (2777) Bracetown Business park, Clonee, Dublin 15, D15 YN2P, Ireland. EU Declaration of Conformity is accessible at www.intouchcares.com. Product reference: PFN

In compliance with Medical Devices Regulations 2002 (SI 2002 No. 618, as amended) (UK MDR 2002) and PPE Regulation (EU) 2016/425 as retained in UK Law and amended. UK Approved Body responsible for PPE UKCA Type Examination (Module B) and Module C2 On-going Conformity Assessment is SATRA Technology Center Limited (AB0321), Wyndham Way, Kettering NN16 8SD, United Kingdom. In compliance with PPE Regulation (EU) 2016/425 as retained in UK Law and amended. UK Declaration of Conformity is accessible at www.intouchcares.com.

This glove product is intended to be worn on the hand to provide a barrier protection against risks associated with contact with certain chemicals, microorganisms & other contaminants. Gloves used for protection against chemotherapy drugs exposure should be selected specifically for the type of drugs being used. Users are advise to review Material Safety Data Sheets for the chemicals being used to determine the required level of protection.

User information sheet is enclosed in this package.

KOSSAN INTERNATIONAL SDN. BHD. (2731784M) Tel +603 3392 3013
Wisma KOSSAN, Lot 782, Jalan Sungai Putus, Off Batu 3rd, Jalan Kapar, 42100 Klang,
Selangor, Malaysia.

ADVENA LIMITED Email info@advena.mt
Tower Business Centre, 2nd Floor, Tower Street, Swatar, BKR 4013, Malta.

UKRP ADVENA LIMITED UK Email info@advenamedical.com
Pure Offices, Plato Close, Tachbrook Park, Warwick CV34 6WE, United Kingdom.

Made in Malaysia



9555256614712

REF
IMCS30BF-XS



Tested for use with chemotherapy drugs using ASTM D6978.

Chemotherapy drugs & chemicals	Breakthrough detection time
Cisplatin 1 mg/ml, Cyclophosphamide (Cytoxan) 20 mg/ml, Cytarabine 100 mg/ml, Doxorubicin (Doxil) 10 mg/ml, Etoposide 20 mg/ml, Fluorouracil 50 mg/ml, Ifosfamide 50 mg/ml, Methotrexate 25 mg/ml, Mitomycin C 0.5 mg/ml, Mitoxantrone 2 mg/ml, Paclitaxel (Taxol) 6 mg/ml, Vincristine sulfate 1 mg/ml	Minimum 240 min
Thiotepa 10 mg/ml	30.2 min
Carmustine (BCNU) 3.3 mg/ml	10.1 min
Fentanyl citrate injection (100 µg/2ml)	Minimum 240 min

Warning: Not recommended for use with Carmustine and Thiotepa.

Chemicals	Level	Mean degradation	Chemicals	Level	Mean degradation
*4% Chlorhexidine Digluconate	6	19.0%	10% Sodium Percarbonate	6	15.4%
40% Sodium Hydroxide (K)	6	-42.9%	10% Acetic Acid	4	66.7%
10-13% Sodium Hypochlorite	6	14.7%	37% Formaldehyde (T)	3	5.0%
50% Sulphuric Acid	6	-20.5%	30% Hydrogen Peroxide (P)	2	22.8%
5% Ethidium Bromide	6	3.4%	25% Ammonium Hydroxide (O)	0	-52.0%
50% Glutaraldehyde	6	27.4%	65% Nitric Acid (M)	0	97.6%
0.1% Phenol	6	33.8%	70% Isopropanol	0	62.2%
1.5% Methanol in Water	6	21.9%	35% Ethanol	0	38.8%
3% Povidone-iodine	6	33.7%	99% Acetic Acid (N)	0	93.9%

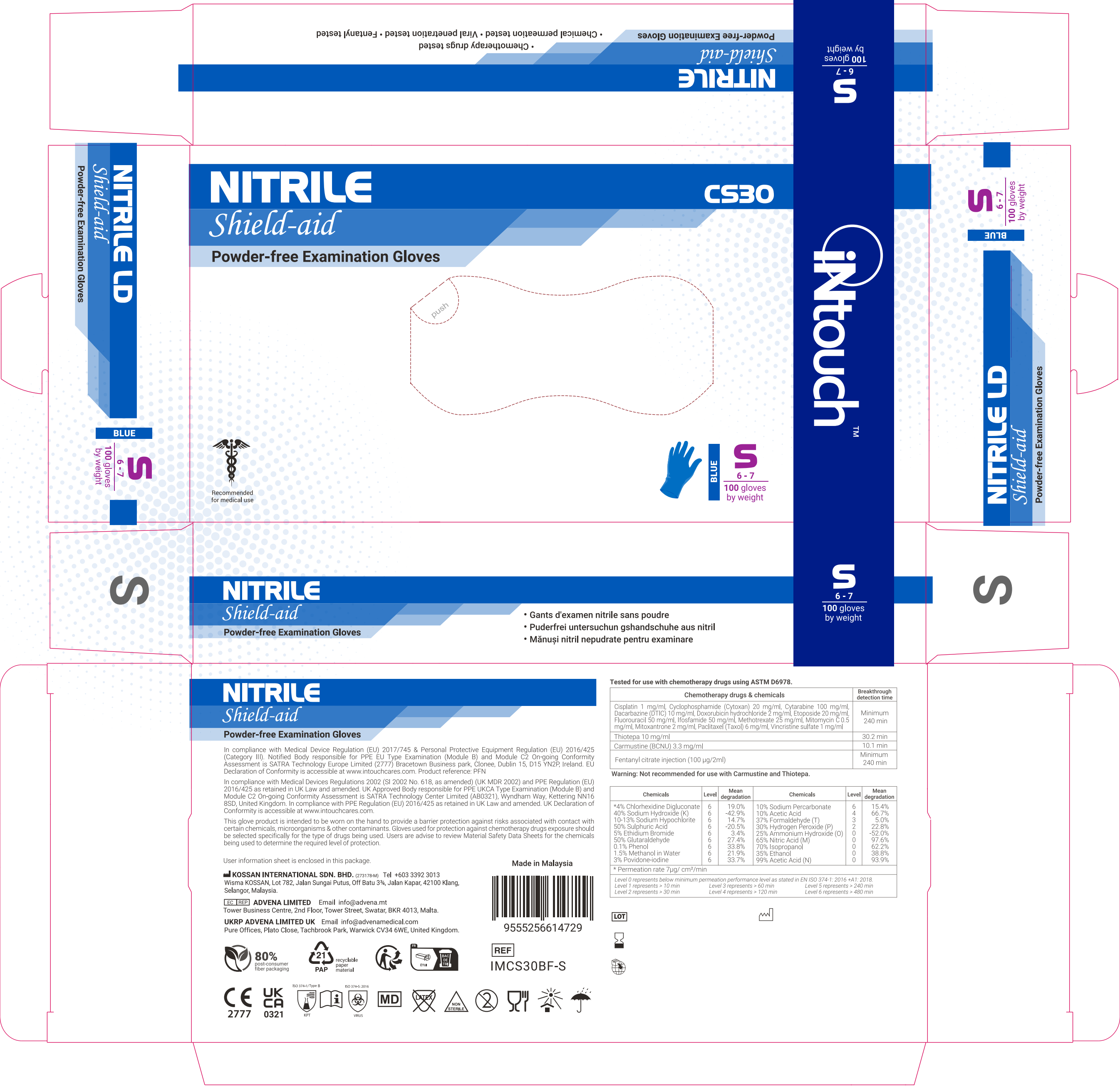
* Permeation rate 7µg/ cm²/min

Level 0 represents below minimum permeation performance level as stated in EN ISO 374-1: 2016 +A1: 2018.
Level 1 represents > 10 min
Level 2 represents > 30 min
Level 3 represents > 60 min
Level 4 represents > 120 min
Level 5 represents > 240 min
Level 6 represents > 480 min

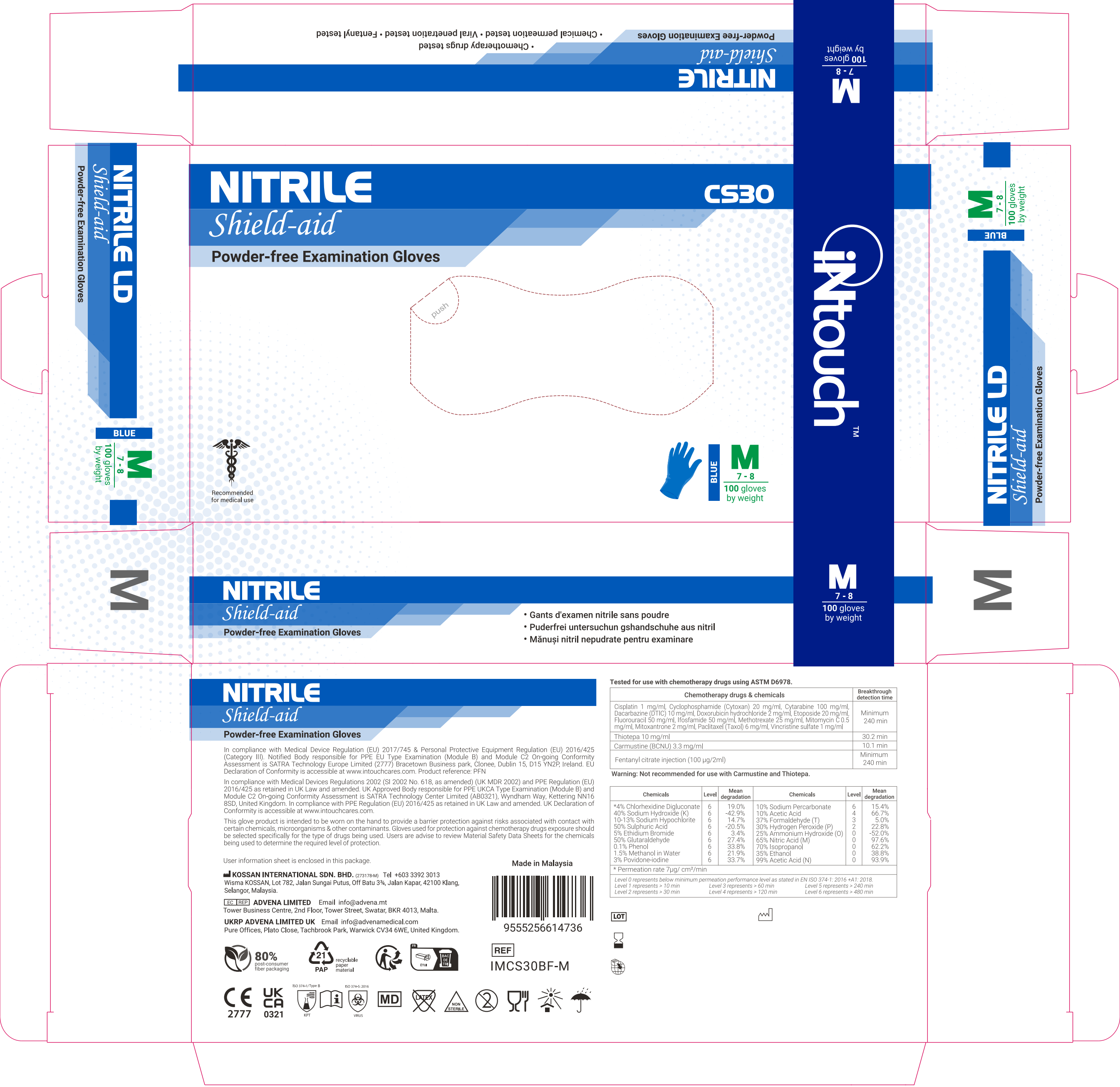
LOT



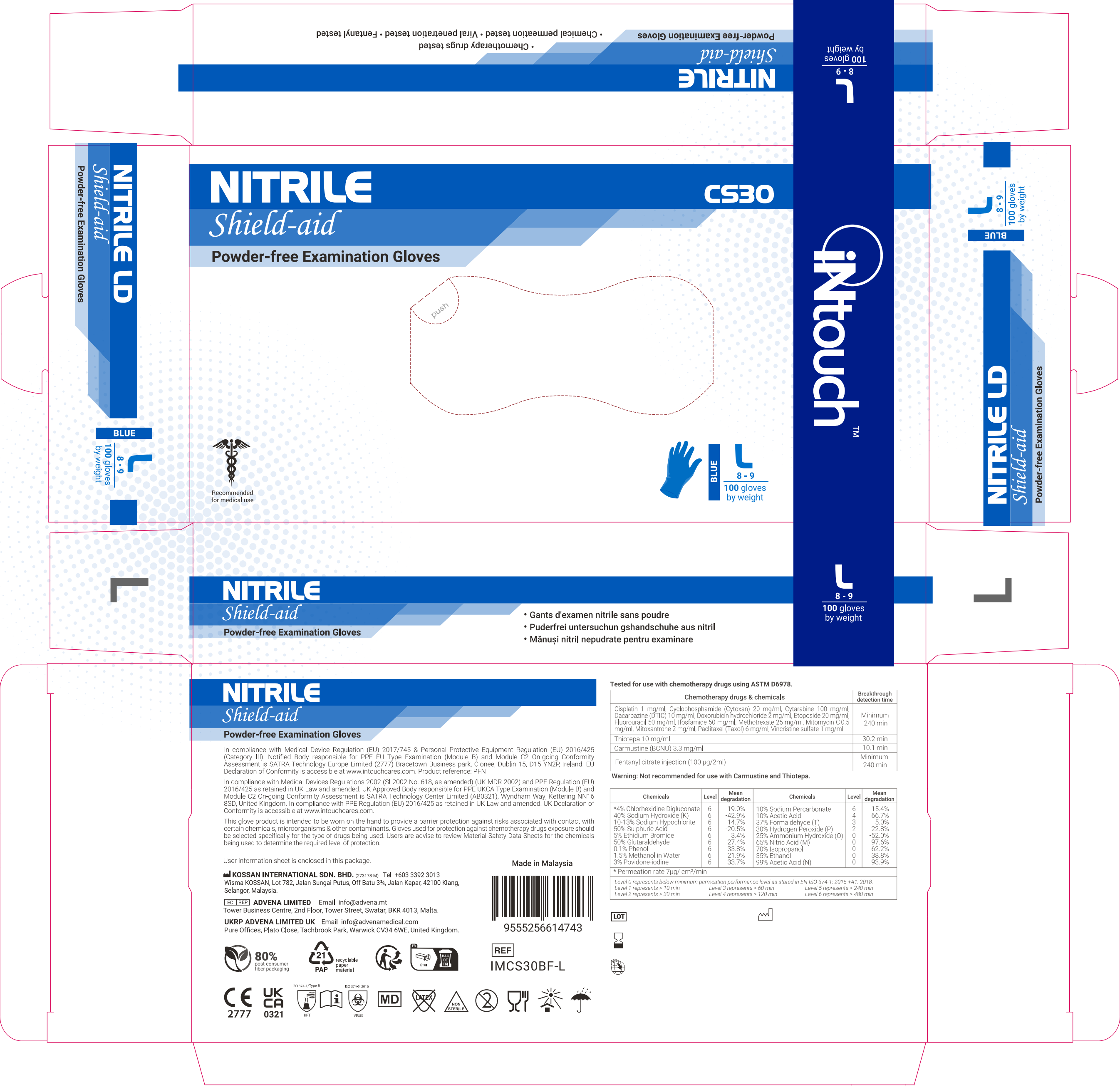
235 x 120 x 45



235 x 120 x 45



235 x 120 x 45



235 x 120 x 45

