Belscan Continental BV
Stokkelaar 4
9160 Lokeren
Belgium
Tel: +32 9 340 56 26
Email: info@belscan.be
Home: www.Belscan.be

PRODUCT INFORMATIE FICHE

	XS	S	M	L	XL	XXL
Onze referentie		9002369	9002370	9002371	9002372	
Omschrijving	Nitril handschoenen		iNtouch N6		AQL 1,5	
	Nitril handschoenen steriel 1 paar iNtouch 30cm					

PRODUCTVERPAKKING

PRODUCT BESCHRIJVING

Materiaal			Nitrile				
Kleur		Blauw					
Karakteristieken		Poedervrij	Steriel		Ambidextrous		
Oppervlakte		Getextureerde vingertop			Gechlorineerd binnenin - Polymeer coating buitenzijde		

MAATVOERING

	XS (5-6)	S (6-7)	M (7-8)	L (8-9)	XL (9-10)	XXL (10-11)	XXXL (11-12)
Breedte		85 ± 10 mm	95 ± 10 mm	106 ± 10 mm	116 ± 10 mm		
Lengte		≥ 295 mm	≥ 295 mm	≥ 295 mm	≥ 295 mm		

MATERIAALDIKTE

	Pols / Manchet	Handpalm	Vingertop	Totaal gewicht (M)			
Dikte	0,08mm	0,10 mm	0,12mm	6,0 gram			

PRODUCT INFORMATIE FICHE

	XS	S	M	L	XL	XXL
Onze referentie		9002369	9002370	9002371	9002372	
Omschrijving	Nitril handschoenen Nitril handschoenen steriel 1 paar iNtouch 30cm					

PRODUCT SPECIFICATIES EN388

EN 388 Mechanische risico's	Slijtage weerstand	Weerstand tegen snijden	Scheurbestendigheid	Doorprik weerstand	Weerstand tegen snijden TDM-test	Impact test	○ EN 388:2016
Level							

PRODUCT SPECIFICATIES EN374

EN 374-1	De handschoenen mogen niet teveel van vorm veranderen, ze mogen ook niet breken of plakken				○	
EN 374-2	Het materiaal mag geen perforaties bevatten				○	
EN 374-3	Chemicaliën mogen niet door het materiaal van de handschoen komen				○	
EN 374-4	Er wordt getest op de tijdsduur en de hoeveelheid chemische stoffen die door de handschoen dringen.e.				○	
EN 374-4	Chemishe stof	Code letter	Permeatie Level		Degradatie		
						○
						○
						○
						○
						○
Accelerators					○	
EN 374-5 Microorganisme dichtheid	De handschoen is goed bestand tegen micro-organismen (virussen, bacteriën en schimmels).				○	EN ISO 374-5:2016 VIRUS
	Test methode	Getest volgens to ISO 16604 - methode B.				

PRODUCT SPECIFICATIES EN16523

EN16523-1	Bepaling van de weerstand van materialen tegen permeatie door chemicaliën - Deel 1: Permeatie door potentieel gevaarlijke vloeibare chemicaliën onder omstandigheden van voortdurend contact	○	

PRODUCT SPECIFICATIES EN455

EN 455 medische handschoenen voor eenmalig gebruik	De handschoen voldoet aan de eisen volgens EN 455-1, EN 455-2, EN 455-3, EN 455-4	✓	EN455
EN 455-1	De handschoen heeft een AQL < 1,5 met betrekking tot de waterretentietest (steekproefinspectie volgens ISO 2859-1, algemeen inspectieniveau I)	✓	EN455-1
EN 455-2:	Hierbij wordt de treksterkte, dikte en pasvorm getest waarbij een minimumnorm van 6 Newton wordt gehanteerd	✓	EN455-2
EN 455-3	In deze biologische evaluatie wordt getest of er schadelijke stoffen aanwezig zijn zoals poeder en micro-organismen.	✓	EN455-3
EN 455-4	Het product wordt getest op de houdbaarheid.	✓	EN455-4

PRODUCT SPECIFICATIES EN21420

ISO EN 21420 Protective gloves	De handschoen voldoet aan de vereisten volgens EN 420 / ISO EN 21420	✓	

PRODUCT INFORMATIE FICHE

	XS	S	M	L	XL	XXL
Onze referentie		9002369	9002370	9002371	9002372	

Omschrijving

Nitril handschoenen

Nitril handschoenen steriel 1 paar
iNtouch 30cm

REGELGEVENDE INFORMATIE

PPE-Regulation (EU) 2016/425				No PPE-Artikel				
MD-Regulation (EU) 2017/745	Klasse I			Steriel				
CE Regulation						BSI 2797	✓	CE
EUROPEAN REPRESENTATIVE	ADVENA LIMITED						✓	EC REP
Contact met voeding (EG) 1935/2004						Niet geschikt contact voeding	○	
LATEX	Bevat geen latex						✓	LATEX
Opslag voorwaarden	Bewaar in originele verpakking op een droge en donkere plaats bij 10°C tot 30°C. Raadpleeg de richtlijnen voor opslag van rubber producten zoals beschreven in ISO2230:2002. Zorg voor een koele, droge en stofvrije opslag, vermijd ventilatie en opslag in de buurt van kopieerapparatuur. Koperionen doen de handschoen verkleuren. Bescherm de handschoenen tegen ultraviolette lichtbronnen, zoals zonlicht en oxiderende middelen. Opslag boven 30°C leidt tot versnelde veroudering en moet vermeden worden.				Houdbaarheid (maanden)	59	✓	
Eenmalig/ dubbel of hergebruik	wegwerp onderzoekshandschoen voor éénmalig gebruik						✓	2
Steriel / Niet Steriel	Niet steriele handshoen						✓	NON STERILE
ASTM F739 ASTM D6978	Symbool dat wordt gebruikt voor SW-chemotherapie geteste handschoenen die ofwel volgens ASTM F739 ofwel volgens ASTM D6978 zijn getest						○	TESTED FOR USE WITH CHEMOTHERAPY DRUGS
REACH Conform	REACH is een verordening van de Europese Unie die is aangenomen ter verbetering van de bescherming van de menselijke gezondheid en het milieu tegen de risico's die chemische stoffen kunnen opleveren, en ter versterking van het concurrentievermogen van de chemische industrie van de EU.						✓	
CE	CE conformiteit						✓	CE
Intrastat nummer	4015120000							
Made in	MALAYSIA							

PRODUCT INFORMATIE FICHE

	XS	S	M	L	XL	XXL
Onze referentie		9002369	9002370	9002371	9002372	
Omschrijving		Nitril handschoenen Nitril handschoenen steriel 1 paar iNtouch 30cm				

LOGISTIEKE INFORMATIE SUBVERPAKKING (DISPENSERDOOS)

Algemene informatie — Materiaal verpakking: Karton

Maatvoering	Stuks per doos	EAN Code	REF code	Lengte (mm)	Breedte (mm)	Hoogte (mm)	Gewicht netto	Gewicht Bruto
XS								
S	1	9555256603761	9002369	250	150	135	860	987
M	1	9555256603778	9002370	250	150	135	900	1027
L	1	9555256603785	9002371	250	150	135	960	1087
XL	1	9555256603792	9002372	250	150	135	1020	1147
XXL								

LOGISTIEKE INFORMATIE OVERVERPAKKING (OVERKARTON)

Algemene informatie — Materiaal verpakking: Karton

Maatvoering	Stuks per karton	EAN Code	REF code	Lengte (mm)	Breedte (mm)	Hoogte (mm)	Gewicht netto	Gewicht Bruto
XS								
S	6	9555256603815	9002369	460	280	260	5,922	7,312
M	6	9555256603822	9002370	460	280	260	6,162	7,552
L	6	9555256603839	9002371	460	280	260	6,522	7,912
XL	6	9555256603846	9002372	460	280	260	6,882	8,272
XXL								

LOGISTIEKE INFORMATIE (EURO)PALLET

Algemene informatie — Pallet: EURO-PALLET

Maatvoering	Kartons per laag	Lagen per Pallet	Netto Hoogte	Bruto hoogte (incl. Euro pallet 14,4cm)	Bruto gewicht (incl. Euro pallet 25kg)
XS					
S	6	6	26	171	288,23kg
M	6	6	26	171	296,87kg
L	6	6	26	171	309,83kg
XL	6	6	26	171	322,79kg
XXL					

PRODUCT INFORMATIE FICHE	XS	S	M	L	XL	XXL
Onze referentie		9002369	9002370	9002371	9002372	
Omschrijving	Nitril handschoenen Nitril handschoenen steriel 1 paar iNtouch 30cm					

KOSSAN
STRETCHING LIMITS • SINCE 1979

KOSSAN INTERNATIONAL SDN. BHD. 199301018440 (273178-M)

EU DECLARATION OF CONFORMITY

We,

Kossan International Sdn Bhd
Wisma Kossan, Lot 782, Jalan Sungai Putus,
Off Batu 3 3/4, Jalan Kapar,
42100 Klang, Selangor, Malaysia.
SRN: MY-MF-000022331

with his EU representative, established in the European Community:

Advena Limited
Tower Business Centre
2nd Floor, Tower Street
Swatar, BKR 4013
Malta
E-mail: info@advena.mt
SRN: *MT-AR-000000234*

Under the sole responsibility as a manufacturer, declare that the following product described hereafter:

Product Description	Size	Brand
Sterile Powder Free Nitrile Examination Gloves, Blue Color Basic UDI-DI: 955 525660 SEPFN NM	XS, S, M, L, XL	iNtouch V Synthetic

is in conformity with the

Medical Device Regulation (EU) 2017/745, under Class Is Medical Device per set out in Rule 1 and Rule 5 of Annex VIII, complying with the European standards EN 455-1:2020+A1:2022, EN 455-2:2015, EN 455-3:2015, and EN 455-4:2009.

Conformity assessment was performed according to Article 52 (7), per set out in Part A of Annex XI of the regulations, under certificate number *742058 R000*.

The conformity assessment is carried out by:

BSI Group The Netherlands B.V. (2797)
Say Building,
John M. Keynesplein 9,
1066 EP Amsterdam,
The Netherlands.

KOSSAN INTERNATIONAL SDN. BHD. 199301018440 (273178-M) *A subsidiary of KOSSAN Group*
Wisma KOSSAN, Lot 782, Jalan Sungai Putus, Off Batu 3¾, Jalan Kapar, 42100 Klang, Selangor, Malaysia.
T +603-3291 2657 **F** +603-3291 0584 **www.kossan.com.my**

Gebruikersaanwijzing

KOSSAN

STRETCHING LIMITS • SINCE 1979

KOSSAN INTERNATIONAL SDN. BHD. 199301018440 (273178-M)

The following quality management system standard requirement are used to demonstrate fulfilment to the General Safety and Performance Requirements set out in Annex I of the MDR Regulation (EU) 2017/745.

ISO 9001:2015
EN ISO 13485:2016

Signature:

Selangor, Malaysia
Issue Place
Stamp:

Name : Cho Sow Fong
Position : Senior Manager, Regulatory Affairs
Date : 03 June 2022

Signed and on behalf of: Kossan International Sdn. Bhd

KOSSAN INTERNATIONAL SDN. BHD. 199301018440 (273178-M) ***A subsidiary of KOSSAN Group***
Wisma KOSSAN, Lot 782, Jalan Sungai Putus, Off Batu 3¾, Jalan Kapar, 42100 Klang, Selangor, Malaysia.
T +603-3291 2657 **F** +603-3291 0584 **www.kossan.com.my**

Deze certificering is geldig voor het volgende product:

	XS	S	M	L	XL	XXL

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STRETCHING LIMITS • SINCE 1979

KOSSAN INTERNATIONAL SDN. BHD. (273178-M)

USER INFORMATION

Product Name : iNtouch V Synthetic (INTW82E and INTW83E)

Product Type : Sterile Powder Free Nitrile Examination Gloves (blue colored)

Available size : XS, S, M, L, XL

Kossan International Sdn Bhd
Wisma Kossan, Lot 782,
Jalan Sungai Putus, Off Batu 3 ¾,
Jalan Kapar 42100 Klang,
Selangor Darul Ehsan, Malaysia.

1) Medical Device Regulation (MDR)

a) This product is classified under **Class I Sterile** Medical Device per Rule 1 and Rule 5 of Annex VIII, meets the provisions of Medical Device Regulation (EU) 2017/745.

b) This product complies with European Standards EN 455-1:2020, EN 455-2:2015, EN 455-3:2015, and EN 455-4:2009.

c) Notified Body responsible for conformity assessment was carried out by BSI Group The Netherlands B.V. (2797), Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands.

2) Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002) – UKCA mark

a) This product is classified under **Class I Sterile** Medical Device per Rule 1 and Rule 5 of Annex IX, meets the provisions of the Council Directive 93/42/EEC, as amended by the Council Directive 2007/47/EC.

b) This product complies with Designated Standards BS EN 455-1:2020, BS EN 455-2:2015, BS EN 455-3:2015, and BS EN 455-4:2009.

c) Approved Body responsible for conformity assessment was carried out by BSI Assurance UK Ltd (AB0086), Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP, United Kingdom.

Dated 01 March 2022

3) Indication For Use (IFU)

Sterile examination gloves are intended to be worn on the hands of healthcare personnel for medical purposes to provide a barrier against potentially infections materials and other contaminants. Sterile examination gloves are intended to be worn only once and permanently discarded after use. This glove is supplied sterile and intended to be used on a single patient during a single procedure/examination only.

4) Usage

For single use only. If re-used:

a) Lost of sterility
b) Extremely high risk of cross-contamination
c) Deterioration of barrier protection
d) Deterioration of glove properties
e) Lost of lot traceability

5) Warnings

a) Do not use if the sealed pouch is punctured, torn or otherwise compromised.
b) Do not use if the glove is visibly torn, frayed or damaged.
c) Do not re-sterilize.

6) Storage conditions

Store under cool and dry conditions. Avoid direct sunlight and heat. The gloves are packed in dispenser suitable for transportation. Keep the gloves in the box when they are not in use.

7) Instruction for Use

a) For maximum comfort, choose the fitting gloves size for your hands.
As examination gloves are ambidextrous, it should be donned according to the correct hand-side as indicated on the inner wrapper.

b) Donning:
- Prior to donning, perform hand hygiene using hand scrub or antimicrobial solution and water.

c) 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 or non-sterile surface.

d) Doffing – Hold glove bead and pull toward the finger until the glove come off

e) These gloves have not been tested against chemotherapy drugs.

8) Precaution for disposal

Dispose of soiled examination gloves in accordance with relevant regulations that practice safe disposal of clinical waste.

Belscan Continental BV
Stokkelaar 4
9160 Lokeren
Belgium
Tel: +32 9 340 56 26
Email: info@belscan.be
Home: www.Belscan.be

FICHE TECHNIQUE DU PRODUIT

	XS	S	M	L	XL	XXL
notre référence		9002369	9002370	9002371	9002372	
Description	Gants Nitrile		iNtouch N6		AQL 1,5	
	Gants en nitrile stérile 1 paire iNtouch 30cm					

L'EMBALLAGE DU PRODUIT

DESCRIPTION DU PRODUIT

Materiel			Nitrile				
Couleur		Bleu					
Caractéristiques		Non Poudré	Sterile		Ambidextre		
Surface		Texturé aux doigts			Chloré à l'intérieur - Revêtement polymère à l'extérieur		

TAILLES

	XS (5-6)	S (6-7)	M (7-8)	L (8-9)	XL (9-10)	XXL (10-11)	XXXL (11-12)
Largeur		85 ± 10 mm	95 ± 10 mm	106 ± 10 mm	116 ± 10 mm		
longueur		≥ 295 mm	≥ 295 mm	≥ 295 mm	≥ 295 mm		

ÉPAISSEUR

	Manchette	Paume de la main	Bouts des doigts	Poids total (M)			
Epaisseur	0,08mm	0,10 mm	0,12mm	6,0 gram			

FICHE TECHNIQUE DU PRODUIT

	XS	S	M	L	XL	XXL
notre référence		9002369	9002370	9002371	9002372	
Description	Gants Nitrile Gants en nitrile stérile 1 paire iNtouch 30cm					

STANDARDISATION EN388

EN 388 Risques mécaniques	Abrasion resistance	Résistance à la coupure de la lame	Résistance à la déchirure	Résistance à la perforation	Résistance à la coupure de la lame Test TDM	Test d'impact	○	EN 388:2016
Niveau								

STANDARDISATION EN374

EN 374-1	Les gants ne doivent pas trop changer de forme, ni se dechirer ou coller.					○	
EN 374-2	Le matériau ne doit pas comporter de perforations					○	
EN 374-3	Les produits chimiques ne doivent pas traverser le matériau des gants.					○	
EN 374-4	Des tests sont effectués sur la durée et la quantité de substances chimiques qui pénètrent dans le gant.					○	
EN 374-4	Produits chimiques	Lettre de code	Perméation niveau		Dégradation		
						○	
						○	
						○	
						○	
						○	
Accélérateurs						○	
EN 374-5 Étanchéité aux micro-organismes	Le gant est étanche aux micro-organismes (virus, bactéries et fungus).					○	EN ISO 374-5:2016 VIRUS
	Méthode d'essai	Essai selon la norme ISO 16604 - méthode B.					

STANDARDISATION EN16523

EN16523-1	Détermination de la résistance des matériaux à la perméation par les produits chimiques - Partie 1 : Perméation par des produits chimiques liquides potentiellement dangereux dans des conditions de contact continu.	○	

STANDARDISATION EN455

EN 455 medical gloves for single use	Le gant répond aux exigences des normes EN 455-1, EN 455-2, EN 455-3, EN 455-4.	✓	EN455
EN 455-1	Le gant a un AQL < 1,5 en ce qui concerne le test de rétention d'eau (inspection par échantillonnage conformément à la norme ISO 2859-1, inspection générale de niveau I).	✓	EN455-1
EN 455-2:	La résistance à la traction, l'épaisseur et l'ajustement sont testés avec une norme minimale de 6 Newtons.	✓	EN455-2
EN 455-3	Cette évaluation biologique recherche la présence de substances nocives telles que la poudre et les micro-organismes.	✓	EN455-3
EN 455-4	Le produit est testé pour sa durée de conservation.	✓	EN455-4

STANDARDISATION EN21420

ISO EN 21420 Gants de protection	Le gant répond aux exigences de la norme EN 420 / ISO EN 21420	✓	

FICHE TECHNIQUE DU PRODUIT

	XS	S	M	L	XL	XXL
notre référence		9002369	9002370	9002371	9002372	

Description

Gants Nitrile

Gants en nitrile stérile 1 paire iNtouch 30cm

AFFAIRES RÉGALIENNES

EPI-Règlement (UE) 2016/425				Non EPI-Article				
Règlement MD (UE) 2017/745	Classe I			Sterile				
Règlement CE					BSI	2797	✓	CE
REPRÉSENTANT EUROPÉEN	ADVENA LIMITED						✓	EC REP
Contact alimentaire (EG) 1935/2004						non approuvé pour le contact alimentaire	○	
LATEX	Ne contient pas de latex						✓	LATEX
Conditions de stockage	Stocker dans l'emballage d'origine dans un endroit sec et sombre entre 10°C et 30°C. Se référer aux directives de stockage des produits en caoutchouc telles que décrites dans la norme ISO2230:2002. S'assurer que le stockage est maintenu au frais, au sec et à l'abri de la poussière, éviter la ventilation et le stockage à proximité d'un équipement de photocopie. Les ions de cuivre décolorent le gant. Protéger les gants contre les sources de lumière ultraviolette, comme la lumière du soleil et les agents oxydants. Un stockage à plus de 30°C entraîne un vieillissement accéléré et doit être évité.				Durée de conservation (mois)	59	✓	
Simple/double/ réutilisable	Gant d'examen à usage unique						✓	2
Sterile / Non Sterile	Gant non stérile						✓	NON STERILE
ASTM F739	Gants de chimiothérapie SW testés soit par ASTM F739 soit par ASTM D6978						○	TESTED FOR USE WITH CHEMOTHERAPY DRUGS
ASTM D6978								
Conforme à REACH	REACH est un règlement de l'Union européenne, adopté pour améliorer la protection de la santé humaine et de l'environnement contre les risques que peuvent présenter les produits chimiques, tout en renforçant la compétitivité de l'industrie chimique européenne.						✓	
CE	Conformité CE						✓	CE
Numéro Intrastat	4015120000							
Fabriqué en	MALAYSIA							

FICHE TECHNIQUE DU PRODUIT

	XS	S	M	L	XL	XXL
notre référence		9002369	9002370	9002371	9002372	

Description

Gants Nitrile

Gants en nitrile stérile 1 paire iNtouch 30cm

LE SOUS-EMBALLAGE DES DONNÉES LOGISTIQUES

Informations générales — Matériel — Carton

Taille	pièces	EAN Code	REF code	Longeur (mm)	Largeur (mm)	Hauteur (mm)	poids net	poids brut
XS								
S	1	9555256603761	9002369	250	150	135	860	987
M	1	9555256603778	9002370	250	150	135	900	1027
L	1	9555256603785	9002371	250	150	135	960	1087
XL	1	9555256603792	9002372	250	150	135	1020	1147
XXL								

DONNÉES LOGISTIQUES EMBALLAGE EXTÉRIEUR

Informations générales — Matériel — Carton

Taille	pièces	EAN Code	REF code	Longeur (mm)	Largeur (mm)	Hauteur (mm)	poids net	poids brut
XS								
S	6	9555256603815	9002369	460	280	260	5,922	7,312
M	6	9555256603822	9002370	460	280	260	6,162	7,552
L	6	9555256603839	9002371	460	280	260	6,522	7,912
XL	6	9555256603846	9002372	460	280	260	6,882	8,272
XXL								

DONNÉES LOGISTIQUES PALETTE

Informations générales — Pallet: EURO-PALLET

Taille	Cartons par couche	Couches par palette	Hauteur de la couche	Hauteur brute (incl. palette Euro 14,4cm)	Poids brut (y compris la palette Euro de 25 kg)
XS					
S	6	6	26	171	288,23kg
M	6	6	26	171	296,87kg
L	6	6	26	171	309,83kg
XL	6	6	26	171	322,79kg
XXL					

FICHE TECHNIQUE DU PRODUIT

	XS	S	M	L	XL	XXL
notre référence		9002369	9002370	9002371	9002372	
Description	Gants Nitrile Gants en nitrile stérile 1 paire iNtouch 30cm					

KOSSAN

STRETCHING LIMITS • SINCE 1979

KOSSAN INTERNATIONAL SDN. BHD. 199301018440 (273178-M)

EU DECLARATION OF CONFORMITY

We,

Kossan International Sdn Bhd
Wisma Kossan, Lot 782, Jalan Sungai Putus,
Off Batu 3 3/4, Jalan Kapar,
42100 Klang, Selangor, Malaysia.
SRN: MY-MF-000022331

with his EU representative, established in the European Community:

Advena Limited
Tower Business Centre
2nd Floor, Tower Street
Swatar, BKR 4013
Malta
E-mail: info@advena.mt
SRN: *MT-AR-000000234*

Under the sole responsibility as a manufacturer, declare that the following product described hereafter:

Product Description	Size	Brand
Sterile Powder Free Nitrile Examination Gloves, Blue Color Basic UDI-DI: 955 525660 SEPFN NM	XS, S, M, L, XL	iNtouch V Synthetic

is in conformity with the

Medical Device Regulation (EU) 2017/745, under Class Is Medical Device per set out in Rule 1 and Rule 5 of Annex VIII, complying with the European standards EN 455-1:2020+A1:2022, EN 455-2:2015, EN 455-3:2015, and EN 455-4:2009.

Conformity assessment was performed according to Article 52 (7), per set out in Part A of Annex XI of the regulations, under certificate number *742058 R000*.

The conformity assessment is carried out by:

BSI Group The Netherlands B.V. (2797)
Say Building,
John M. Keynesplein 9,
1066 EP Amsterdam,
The Netherlands.

KOSSAN INTERNATIONAL SDN. BHD. 199301018440 (273178-M) *A subsidiary of KOSSAN Group*
Wisma KOSSAN, Lot 782, Jalan Sungai Putus, Off Batu 3¾, Jalan Kapar, 42100 Klang, Selangor, Malaysia.
T +603-3291 2657 **F** +603-3291 0584 **www.kossan.com.my**

KOSSAN

STRETCHING LIMITS • SINCE 1979

KOSSAN INTERNATIONAL SDN. BHD. 199301018440 (273178-M)

The following quality management system standard requirement are used to demonstrate fulfilment to the General Safety and Performance Requirements set out in Annex I of the MDR Regulation (EU) 2017/745.

ISO 9001:2015
EN ISO 13485:2016

Signature:

Selangor, Malaysia
Issue Place
Stamp:

Name : Cho Sow Fong
Position : Senior Manager, Regulatory Affairs
Date : 03 June 2022

Signed and on behalf of: Kossan International Sdn. Bhd

KOSSAN

KOSSAN INTERNATIONAL SDN. BHD. (273178-M)

F

STRETCHING LIMITS • SINCE 1979

USER INFORMATION

Product Name : iNtouch V Synthetic (INTW82E and INTW83E)

Product Type : Sterile Powder Free Nitrile Examination Gloves (blue colored)

Available size : XS, S, M, L, XL

Kossan International Sdn Bhd
Wisma Kossan, Lot 782,
Jalan Sungai Putus, Off Batu 3 ¾,
Jalan Kapar 42100 Klang,
Selangor Darul Ehsan, Malaysia.

1) Medical Device Regulation (MDR)

a) This product is classified under **Class I Sterile** Medical Device per Rule 1 and Rule 5 of Annex VIII, meets the provisions of Medical Device Regulation (EU) 2017/745.

b) This product complies with European Standards EN 455-1:2020, EN 455-2:2015, EN 455-3:2015, and EN 455-4:2009.

c) Notified Body responsible for conformity assessment was carried out by BSI Group The Netherlands B.V. (2797), Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands.

2) Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002) – UKCA mark

a) This product is classified under **Class I Sterile** Medical Device per Rule 1 and Rule 5 of Annex IX, meets the provisions of the Council Directive 93/42/EEC, as amended by the Council Directive 2007/47/EC.

b) This product complies with Designated Standards BS EN 455-1:2020, BS EN 455-2:2015, BS EN 455-3:2015, and BS EN 455-4:2009.

c) Approved Body responsible for conformity assessment was carried out by BSI Assurance UK Ltd (AB0086), Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP, United Kingdom.

KOSSAN

STRETCHING LIMITS • SINCE 1979

KOSSAN INTERNATIONAL SDN. BHD. (273178-M)

3) Indication For Use (IFU)

Sterile examination gloves are intended to be worn on the hands of healthcare personnel for medical purposes to provide a barrier against potentially infections materials and other contaminants. Sterile examination gloves are intended to be worn only once and permanently discarded after use. This glove is supplied sterile and intended to be used on a single patient during a single procedure/examination only.

4) Usage

For single use only. If re-used:

a) Lost of sterility
b) Extremely high risk of cross-contamination
c) Deterioration of barrier protection
d) Deterioration of glove properties
e) Lost of lot traceability

5) Warnings

a) Do not use if the sealed pouch is punctured, torn or otherwise compromised.
b) Do not use if the glove is visibly torn, frayed or damaged.
c) Do not re-sterilize.

6) Storage conditions

Store under cool and dry conditions. Avoid direct sunlight and heat. The gloves are packed in dispenser suitable for transportation. Keep the gloves in the box when they are not in use.

7) Instruction for Use

a) For maximum comfort, choose the fitting gloves size for your hands.
As examination gloves are ambidextrous, it should be donned according to the correct hand-side as indicated on the inner wrapper.

b) Donning:
- Prior to donning, perform hand hygiene using hand scrub or antimicrobial solution and water.

c) 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 or non-sterile surface.

d) Doffing – Hold glove bead and pull toward the finger until the glove come off

e) These gloves have not been tested against chemotherapy drugs.

8) Precaution for disposal

Dispose of soiled examination gloves in accordance with relevant regulations that practice safe disposal of clinical waste.

Belscan Continental BV
Stokkelaar 4
9160 Lokeren
Belgium
Tel: +32 9 340 56 26
Email: info@belscan.be
Home: www.Belscan.be

PRODUCT DATA SHEET

	XS	S	M	L	XL	XXL
Our reference		9002369	9002370	9002371	9002372	
Description	Nitrile Gloves		iNtouch N6		AQL 1,5	
	Nitrile gloves sterile 1 pair iNtouch 30cm					

PRODUCT PACKAGING IMAGE

PRODUCT DESCRIPTION

Material			Nitrile				
Colour		Blue					
Characteristics		Powderfree	Sterile		Ambidextrous		
Surface		Finger Textured			Chlorinated inside - Polymer coated outside		

SIZES

	XS (5-6)	S (6-7)	M (7-8)	L (8-9)	XL (9-10)	XXL (10-11)	XXXL (11-12)
Width		85 ± 10 mm	95 ± 10 mm	106 ± 10 mm	116 ± 10 mm		
length		≥ 295 mm	≥ 295 mm	≥ 295 mm	≥ 295 mm		

THICKNESS

	Cuff	Palm	Fingertips	Overal weight (M)			
Thickness	0,08mm	0,10 mm	0,12mm	6,0 gram			

PRODUCT DATA SHEET

	XS	S	M	L	XL	XXL
Our reference		9002369	9002370	9002371	9002372	

Description

Nitrile Gloves

Nitrile gloves sterile 1 pair iNtouch
30cm

STANDARDISATION EN388

EN 388 Mechanical risks	Abrasion resistance	Blade cut resistance	Tear resistance	Punture resistance	Blad cut resistance TDM-test	Impact test	○
Level							

STANDARDISATION EN374

EN 374-1	The gloves must not change their shape too much, nor must they break or stick.					○	
EN 374-2	The material must not contain any perforations					○	
EN 374-3	Chemicals must not pass through the glove material					○	
EN 374-4	Tests are carried out on the duration and the amount of chemical substances that penetrate the glove.					○	
EN 374-4	Chemical	Code letter	Permeation level		Degradation		
						○	
						○	
						○	
						○	
						○	
Accelerators						○	
EN 374-5 Microorganism tightness	The glove is tight against microorganisms (viral, bacteria and fungi).					○	
	Testing method	Test according to ISO 16604 - method B.					

STANDARDISATION EN16523

EN16523-1	Determination of material resistance to permeation by chemicals - Part 1: Permeation by potentially hazardous liquid chemicals under conditions of continuous contact	○	

STANDARDISATION EN455

EN 455 medical gloves for single use	The glove meets the requirements according to EN 455-1, EN 455-2, EN 455-3, EN 455-4	✓	EN455
EN 455-1	The glove has an AQL < 1.5 in regards to the water retention test (sampling inspection in acc. to ISO 2859-1, general Inspection Level I)	✓	EN455-1
EN 455-2:	The tensile strength, thickness and fit is tested with a minimum standard of 6 Newtons.	✓	EN455-2
EN 455-3	This biological evaluation tests for the presence of harmful substances such as powder and micro-organisms.	✓	EN455-3
EN 455-4	The product tested shelf life	✓	EN455-4

STANDARDISATION EN21420

ISO EN 21420 Protective gloves	The glove meets the requirements according to EN 420 / ISO EN 21420	✓	

PRODUCT DATA SHEET

	XS	S	M	L	XL	XXL
Our reference		9002369	9002370	9002371	9002372	
Description	Nitrile Gloves Nitrile gloves sterile 1 pair iNtouch 30cm					

REGALUTORY AFFAIRS

PPE-Regulation (EU) 2016/425				No PPE-Article				
MD-Regulation (EU) 2017/745	Class I			Sterile				
CE Regulation						BSI 2797	✓	CE
EUROPEAN REPRESENTATIVE				ADVENA LIMITED			✓	EC REP
Food Contact (EG) 1935/2004						not approved for food contact	○	
LATEX	Does not contain latex						✓	LATEX
Storage conditions	Store in original packaging in a dry and dark place at 10°C to 30°C. Refer to guidelines of storage of rubber product as decribed in ISO2230:2002. Ensure that storage is kept cool, dry and dust-free, avoid ventilation and storage close to phocopy equipment. Copper-ions discolour the glove. Protect gloves against ultraviolet light sources, as sunlight and oxidizing agents. Storage above 30°C will lead to accelerated aging and should be avoided.				Shelf life (months)	59	✓	
Single/double/Reusable	Examination glove for single use						✓	
Sterile / Non Sterile	Sterile glove						✓	NON STERILE
ASTM F739	Symbol used for SW chemotherapy tested gloves that have been tested either by ASTM F739 or by ASTM D6978						○	TESTED FOR USE WITH CHEMOTHERAPY DRUGS
ASTM D6978								
REACH Compliant	REACH is a regulation of the European Union, adopted to improve the protection of human health and the environment from the risks that can be posed by chemicals, while enhancing the competitiveness of the EU chemicals industry.						✓	
CE	CE conformoty						✓	CE
Intrastat number	4015120000							
Made in	MALAYSIA							

PRODUCT DATA SHEET

	XS	S	M	L	XL	XXL
Our reference		9002369	9002370	9002371	9002372	

Description

Nitrile Gloves

Nitrile gloves sterile 1 pair iNtouch 30cm

LOGISTIC DATA SALES UNIT

General information Material Carton

Size	pieces	EAN Code	REF code	Length (mm)	Width (mm)	Heigth (mm)	Net weight	Gross weight
XS								
S	1	9555256603761	9002369	250	150	135	860	987
M	1	9555256603778	9002370	250	150	135	900	1027
L	1	9555256603785	9002371	250	150	135	960	1087
XL	1	9555256603792	9002372	250	150	135	1020	1147
XXL								

LOGISTIC DATA OUTER PACKAGING

General information Material Carton

Size	pieces	EAN Code	REF code	Length (mm)	Width (mm)	Heigth (mm)	Net weight	Gross weight
XS								
S	6	9555256603815	9002369	460	280	260	5,922	7,312
M	6	9555256603822	9002370	460	280	260	6,162	7,552
L	6	9555256603839	9002371	460	280	260	6,522	7,912
XL	6	9555256603846	9002372	460	280	260	6,882	8,272
XXL								

LOGISTIC DATA PALLET

General information Pallet: EURO-PALLET

Size	Cartons per layer	Layers per pallet	Netto height	Gross Heigth (incl. Euro pallet 14,4cm)	Gross weight (incl. Euro pallet 25kg)
XS					
S	6	6	26	171	288,23kg
M	6	6	26	171	296,87kg
L	6	6	26	171	309,83kg
XL	6	6	26	171	322,79kg
XXL					

PRODUCT DATA SHEET	XS	S	M	L	XL	XXL
Our reference		9002369	9002370	9002371	9002372	
Description	Nitrile Gloves Nitrile gloves sterile 1 pair iNtouch 30cm					

KOSSAN
STRETCHING LIMITS • SINCE 1979

KOSSAN INTERNATIONAL SDN. BHD. 199301018440 (273178-M)

EU DECLARATION OF CONFORMITY

We,

Kossan International Sdn Bhd
Wisma Kossan, Lot 782, Jalan Sungai Putus,
Off Batu 3 3/4, Jalan Kapar,
42100 Klang, Selangor, Malaysia.
SRN: MY-MF-000022331

with his EU representative, established in the European Community:

Advena Limited
Tower Business Centre
2nd Floor, Tower Street
Swatar, BKR 4013
Malta
E-mail: info@advena.mt
SRN: *MT-AR-000000234*

Under the sole responsibility as a manufacturer, declare that the following product described hereafter:

Product Description	Size	Brand
Sterile Powder Free Nitrile Examination Gloves, Blue Color Basic UDI-DI: 955 525660 SEPFN NM	XS, S, M, L, XL	iNtouch V Synthetic

is in conformity with the

Medical Device Regulation (EU) 2017/745, under Class Is Medical Device per set out in Rule 1 and Rule 5 of Annex VIII, complying with the European standards EN 455-1:2020+A1:2022, EN 455-2:2015, EN 455-3:2015, and EN 455-4:2009.

Conformity assessment was performed according to Article 52 (7), per set out in Part A of Annex XI of the regulations, under certificate number *742058 R000*.

The conformity assessment is carried out by:

BSI Group The Netherlands B.V. (2797)
Say Building,
John M. Keynesplein 9,
1066 EP Amsterdam,
The Netherlands.

KOSSAN

STRETCHING LIMITS • SINCE 1979

KOSSAN INTERNATIONAL SDN. BHD. 199301018440 (273178-M)

The following quality management system standard requirement are used to demonstrate fulfilment to the General Safety and Performance Requirements set out in Annex I of the MDR Regulation (EU) 2017/745.

ISO 9001:2015
EN ISO 13485:2016

Signature:

Selangor, Malaysia
Issue Place
Stamp:

Name : Cho Sow Fong
Position : Senior Manager, Regulatory Affairs
Date : 03 June 2022

Signed and on behalf of: Kossan International Sdn. Bhd

KOSSAN INTERNATIONAL SDN. BHD. 199301018440 (273178-M) ***A subsidiary of KOSSAN Group***
Wisma KOSSAN, Lot 782, Jalan Sungai Putus, Off Batu 3¾, Jalan Kapar, 42100 Klang, Selangor, Malaysia.
T +603-3291 2657 **F** +603-3291 0584 **www.kossan.com.my**

This certification is valid for the following product:

	XS	S	M	L	XL	XXL

KOSSAN

KOSSAN INTERNATIONAL SDN. BHD. (273178-M)

STRETCHING LIMITS • SINCE 1979

USER INFORMATION

Product Name : iNtouch V Synthetic (INTW82E and INTW83E)

Product Type : Sterile Powder Free Nitrile Examination Gloves (blue colored)

Available size : XS, S, M, L, XL

Kossan International Sdn Bhd
Wisma Kossan, Lot 782,
Jalan Sungai Putus, Off Batu 3 ¾,
Jalan Kapar 42100 Klang,
Selangor Darul Ehsan, Malaysia.

1) Medical Device Regulation (MDR)

a) This product is classified under **Class I Sterile** Medical Device per Rule 1 and Rule 5 of Annex VIII, meets the provisions of Medical Device Regulation (EU) 2017/745.

b) This product complies with European Standards EN 455-1:2020, EN 455-2:2015, EN 455-3:2015, and EN 455-4:2009.

c) Notified Body responsible for conformity assessment was carried out by BSI Group The Netherlands B.V. (2797), Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands.

2) Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002) – UKCA mark

a) This product is classified under **Class I Sterile** Medical Device per Rule 1 and Rule 5 of Annex IX, meets the provisions of the Council Directive 93/42/EEC, as amended by the Council Directive 2007/47/EC.

b) This product complies with Designated Standards BS EN 455-1:2020, BS EN 455-2:2015, BS EN 455-3:2015, and BS EN 455-4:2009.

c) Approved Body responsible for conformity assessment was carried out by BSI Assurance UK Ltd (AB0086), Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP, United Kingdom.

3) Indication For Use (IFU)

Sterile examination gloves are intended to be worn on the hands of healthcare personnel for medical purposes to provide a barrier against potentially infections materials and other contaminants. Sterile examination gloves are intended to be worn only once and permanently discarded after use. This glove is supplied sterile and intended to be used on a single patient during a single procedure/examination only.

4) Usage

For single use only. If re-used:

a) Lost of sterility
b) Extremely high risk of cross-contamination
c) Deterioration of barrier protection
d) Deterioration of glove properties
e) Lost of lot traceability

5) Warnings

a) Do not use if the sealed pouch is punctured, torn or otherwise compromised.
b) Do not use if the glove is visibly torn, frayed or damaged.
c) Do not re-sterilize.

6) Storage conditions

Store under cool and dry conditions. Avoid direct sunlight and heat. The gloves are packed in dispenser suitable for transportation. Keep the gloves in the box when they are not in use.

7) Instruction for Use

a) For maximum comfort, choose the fitting gloves size for your hands.
As examination gloves are ambidextrous, it should be donned according to the correct hand-side as indicated on the inner wrapper.

b) Donning:
- Prior to donning, perform hand hygiene using hand scrub or antimicrobial solution and water.

c) 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 or non-sterile surface.

d) Doffing – Hold glove bead and pull toward the finger until the glove come off

e) These gloves have not been tested against chemotherapy drugs.

8) Precaution for disposal

Dispose of soiled examination gloves in accordance with relevant regulations that practice safe disposal of clinical waste.

Belscan Continental BV
Stokkelaar 4
9160 Lokeren
Belgium
Telefon: +32 9 340 56 26
Email: info@belscan.be
Home: www.Belscan.be

PRODUKTDATENBLATT

	XS	S	M	L	XL	XXL
Unser Referenz		9002369	9002370	9002371	9002372	
Beschreibung	Nitril-Handschuhe		iNtouch N6		AQL 1,5	
	Nitrilhandschuhe steril 1 Paar iNtouch 30cm					

BILD DER PRODUKTVERPACKUNG

PRODUKTBESCHREIBUNG

Material			nitril				
Farbe		blau					
Characteristics		puderfrei	steril		beidhändig		
Surface		Finger texturiert			innen gechlort - außen polymerbeschichtet		

GRÖSSEN

	XS (5-6)	S (6-7)	M (7-8)	L (8-9)	XL (9-10)	XXL (10-11)	XXXL (11-12)
Breite		85 ± 10 mm	95 ± 10 mm	106 ± 10 mm	116 ± 10 mm		
Länge		≥ 295 mm	≥ 295 mm	≥ 295 mm	≥ 295 mm		

DICKEN

	Manschette	Handfläche	Fingerspitzen	Gesamtgewicht (M)			
Dicken	0,08mm	0,10 mm	0,12mm	6,0 gram			

PRODUKTDATENBLATT

	XS	S	M	L	XL	XXL
Unser Referenz		9002369	9002370	9002371	9002372	

Beschreibung

Nitril-Handschuhe

Nitrilhandschuhe steril 1 Paar iNtouch 30cm

NORMIERUNG EN388

EN 388 Mechanische Risiken	Abriebfestigkeit	Klingenschnitt-festigkeit	Reißfestigkeit	Durchstich-festigkeit	Schnittfestigkeit TDM-Test	Stoßeinwirkung-sschutz	○	EN 388:2016
Level								

NORMIERUNG EN374

EN 374-1	Die Handschuhe dürfen ihre Form nicht zu stark verändern, sie dürfen nicht brechen oder kleben.					○	
EN 374-2	Das Material darf keine Perforationen aufweisen.					○	
EN 374-3	Chemikalien dürfen nicht durch das Handschuhmaterial dringen.					○	
EN 374-4	Getestet werden die Dauer und die Menge der chemischen Substanzen, die den Handschuh durchdringen.					○	
EN 374-4	Chemikalien	Kennbuchstabe	Durchlässigkeit Niveau		Degradierung		
						○	
						○	
						○	
						○	
						○	
Beschleuniger						○	
EN 374-5 Dichtheit gegenüber Mikroorganismen	Der Handschuh ist dicht gegen Mikroorganismen (Viren, Bakterien und Pilze).					○	EN ISO 374-5:2016 VIRUS
	Prüfmethode	Prüfung nach ISO 16604 - Methode B.					

NORMIERUNG EN16523

EN16523-1	Bestimmung der Beständigkeit von Materialien gegen die Permeation von Chemikalien - Teil 1: Permeation durch potenziell gefährliche flüssige Chemikalien unter Bedingungen des Dauerkontakts	○	

NORMIERUNG EN455

EN 455 medizinische Handschuhe zum	Der Handschuh erfüllt die Anforderungen nach EN 455-1, EN 455-2, EN 455-3, EN 455-4	✓	EN455
EN 455-1	Der Handschuh hat einen AQL < 1,5 in Bezug auf den Wasserrückhaltetest (Stichprobenprüfung nach ISO 2859-1, allgemeines Inspektionsniveau I)	✓	EN455-1
EN 455-2:	Die Zugfestigkeit, Dicke und Passform wird mit einem Mindeststandard von 6 Newton geprüft.	✓	EN455-2
EN 455-3	Bei dieser biologischen Bewertung wird auf das Vorhandensein von Schadstoffen wie Pulver und Mikroorganismen getestet.	✓	EN455-3
EN 455-4	Die geprüfte Haltbarkeit des Produkts	✓	EN455-4

NORMIERUNG EN21420

ISO EN 21420 Protective gloves	Der Handschuh erfüllt die Anforderungen nach EN 420 / ISO EN 21420	✓	

PRODUKTDATENBLATT

	XS	S	M	L	XL	XXL
Unser Referenz		9002369	9002370	9002371	9002372	
Beschreibung	Nitril-Handschuhe Nitrilhandschuhe steril 1 Paar iNtouch 30cm					

REGALUTORY AFFAIRS

PSA-Verordnung (EU) 2016/42				No PPE-Article				
MD-Verordnung (EU) 2017/745	Klasse I			Steril				
CE-Verordnung						BSI 2797	✓	CE
EU-Bevollmächtigter	ADVENA LIMITED						✓	EC REP
Lebensmittelkontakt (EG) 1935/2004						nicht für den Kontakt mit Lebensmitteln	○	
LATEX	Enthält keinen Latex						✓	LATEX
Lagerbedingungen	In der Originalverpackung an einem trockenen und dunklen Ort bei 10°C bis 30°C lagern. Beachten Sie die Richtlinien zur Lagerung von Gummiprodukten gemäß ISO2230:2002. Stellen Sie sicher, dass die Lagerung kühl, trocken und staubfrei erfolgt, vermeiden Sie Belüftung und die Lagerung in der Nähe von Kopiergeräten. Kupferionen verfärben den Handschuh. Schützen Sie die Handschuhe vor ultravioletten Lichtquellen, wie Sonnenlicht und Oxidationsmitteln. Eine Lagerung bei über 30°C führt zu einer beschleunigten Alterung und sollte vermieden werden.				Haltbarkeitsdauer (Monate)	59	✓	
Einmalig/Doppelt/ Wiederverwendbar	Untersuchungshandschuh für den einmaligen Gebrauch						✓	2
steril / unsteril	Nicht steriler Handschuh						✓	NON STERILE
ASTM F739	SW chemotherapiegeprüfte Handschuhe, die entweder nach ASTM F739 oder nach ASTM D6978 getestet wurden						○	TESTED FOR USE WITH CHEMOTHERAPY DRUGS
ASTM D6978								
REACH Verordnung	REACH ist eine Verordnung der Europäischen Union, die erlassen wurde, um den Schutz der menschlichen Gesundheit und der Umwelt vor den Risiken, die von Chemikalien ausgehen können, zu verbessern und gleichzeitig die Wettbewerbsfähigkeit der chemischen Industrie in der EU zu stärken.						✓	
CE	CE-Konformität						✓	CE
Intrastat number	4015120000							
Herkunftsland	MALAYSIA							

PRODUKTDATENBLATT

	XS	S	M	L	XL	XXL
Unser Referenz		9002369	9002370	9002371	9002372	

Description

Nitril-Handschuhe

Nitrilhandschuhe steril 1 Paar iNtouch 30cm

LOGISTISCHE DATEN-UNTERVERPACKUNGEN

Allgemeine Informationen — Material: Karton

Größe	Anzahl	EAN Code	REF code	Länge (mm)	Breite (mm)	Höhe (mm)	Netto gewicht	Brutto gewicht
XS								
S	1	9555256603761	9002369	250	150	135	860	987
M	1	9555256603778	9002370	250	150	135	900	1027
L	1	9555256603785	9002371	250	150	135	960	1087
XL	1	9555256603792	9002372	250	150	135	1020	1147
XXL								

LOGISTISCHE DATEN UMVERPACKUNG

Allgemeine Informationen — Material: Karton

Größe	Anzahl	EAN Code	REF code	Länge (mm)	Breite (mm)	Höhe (mm)	Netto gewicht	Brutto gewicht
XS								
S	6	9555256603815	9002369	460	280	260	5,922	7,312
M	6	9555256603822	9002370	460	280	260	6,162	7,552
L	6	9555256603839	9002371	460	280	260	6,522	7,912
XL	6	9555256603846	9002372	460	280	260	6,882	8,272
XXL								

LOGISTISCHE DATEN (EURO)PALLET

Allgemeine Informationen — Palette: EURO-PALLET

Größe	Kartons pro Lage	Lagen pro Palette	Netto Höhe	Brutto höhe (inkl. Euro pallet 14,4cm)	Bruttogewicht (inkl. Euro pallet 25kg)
XS					
S	6	6	26	171	288,23kg
M	6	6	26	171	296,87kg
L	6	6	26	171	309,83kg
XL	6	6	26	171	322,79kg
XXL					

PRODUKTDATENBLATT	XS	S	M	L	XL	XXL
Unser Referenz		9002369	9002370	9002371	9002372	
Description	Nitril-Handschuhe Nitrilhandschuhe steril 1 Paar iNtouch 30cm					

KOSSAN

STRETCHING LIMITS • SINCE 1979

KOSSAN INTERNATIONAL SDN. BHD. 199301018440 (273178-M)

EU DECLARATION OF CONFORMITY

We,

Kossan International Sdn Bhd
Wisma Kossan, Lot 782, Jalan Sungai Putus,
Off Batu 3 3/4, Jalan Kapar,
42100 Klang, Selangor, Malaysia.
SRN: MY-MF-000022331

with his EU representative, established in the European Community:

Advena Limited
Tower Business Centre
2nd Floor, Tower Street
Swatar, BKR 4013
Malta
E-mail: info@advena.mt
SRN: *MT-AR-000000234*

Under the sole responsibility as a manufacturer, declare that the following product described hereafter:

Product Description	Size	Brand
Sterile Powder Free Nitrile Examination Gloves, Blue Color Basic UDI-DI: 955 525660 SEPFN NM	XS, S, M, L, XL	iNtouch V Synthetic

is in conformity with the

Medical Device Regulation (EU) 2017/745, under Class Is Medical Device per set out in Rule 1 and Rule 5 of Annex VIII, complying with the European standards EN 455-1:2020+A1:2022, EN 455-2:2015, EN 455-3:2015, and EN 455-4:2009.

Conformity assessment was performed according to Article 52 (7), per set out in Part A of Annex XI of the regulations, under certificate number *742058 R000*.

The conformity assessment is carried out by:

BSI Group The Netherlands B.V. (2797)
Say Building,
John M. Keynesplein 9,
1066 EP Amsterdam,
The Netherlands.

KOSSAN INTERNATIONAL SDN. BHD. 199301018440 (273178-M) *A subsidiary of KOSSAN Group*
Wisma KOSSAN, Lot 782, Jalan Sungai Putus, Off Batu 3¾, Jalan Kapar, 42100 Klang, Selangor, Malaysia.
T +603-3291 2657 **F** +603-3291 0584 **www.kossan.com.my**

KOSSAN

STRETCHING LIMITS • SINCE 1979

KOSSAN INTERNATIONAL SDN. BHD. 199301018440 (273178-M)

The following quality management system standard requirement are used to demonstrate fulfilment to the General Safety and Performance Requirements set out in Annex I of the MDR Regulation (EU) 2017/745.

ISO 9001:2015
EN ISO 13485:2016

Signature:

Selangor, Malaysia
Issue Place
Stamp:

Name : Cho Sow Fong
Position : Senior Manager, Regulatory Affairs
Date : 03 June 2022

Signed and on behalf of: Kossan International Sdn. Bhd

KOSSAN INTERNATIONAL SDN. BHD. 199301018440 (273178-M) ***A subsidiary of KOSSAN Group***
Wisma KOSSAN, Lot 782, Jalan Sungai Putus, Off Batu 3¾, Jalan Kapar, 42100 Klang, Selangor, Malaysia.
T +603-3291 2657 **F** +603-3291 0584 **www.kossan.com.my**

Diese Zertifizierung gilt für folgendes Produkt:

	XS	S	M	L	XL	XXL

Unsere Referenznummern:

KOSSAN

KOSSAN INTERNATIONAL SDN. BHD. (273178-M)

STRETCHING LIMITS • SINCE 1979

USER INFORMATION

Product Name : iNtouch V Synthetic (INTW82E and INTW83E)

Product Type : Sterile Powder Free Nitrile Examination Gloves (blue colored)

Available size : XS, S, M, L, XL

Kossan International Sdn Bhd
Wisma Kossan, Lot 782,
Jalan Sungai Putus, Off Batu 3 ¾,
Jalan Kapar 42100 Klang,
Selangor Darul Ehsan, Malaysia.

1) Medical Device Regulation (MDR)

a) This product is classified under **Class I Sterile** Medical Device per Rule 1 and Rule 5 of Annex VIII, meets the provisions of Medical Device Regulation (EU) 2017/745.

b) This product complies with European Standards EN 455-1:2020, EN 455-2:2015, EN 455-3:2015, and EN 455-4:2009.

c) Notified Body responsible for conformity assessment was carried out by BSI Group The Netherlands B.V. (2797), Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands.

2) Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002) – UKCA mark

a) This product is classified under **Class I Sterile** Medical Device per Rule 1 and Rule 5 of Annex IX, meets the provisions of the Council Directive 93/42/EEC, as amended by the Council Directive 2007/47/EC.

b) This product complies with Designated Standards BS EN 455-1:2020, BS EN 455-2:2015, BS EN 455-3:2015, and BS EN 455-4:2009.

c) Approved Body responsible for conformity assessment was carried out by BSI Assurance UK Ltd (AB0086), Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP, United Kingdom.

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3) Indication For Use (IFU)

Sterile examination gloves are intended to be worn on the hands of healthcare personnel for medical purposes to provide a barrier against potentially infections materials and other contaminants. Sterile examination gloves are intended to be worn only once and permanently discarded after use. This glove is supplied sterile and intended to be used on a single patient during a single procedure/examination only.

4) Usage

For single use only. If re-used:

a) Lost of sterility
b) Extremely high risk of cross-contamination
c) Deterioration of barrier protection
d) Deterioration of glove properties
e) Lost of lot traceability

5) Warnings

a) Do not use if the sealed pouch is punctured, torn or otherwise compromised.
b) Do not use if the glove is visibly torn, frayed or damaged.
c) Do not re-sterilize.

6) Storage conditions

Store under cool and dry conditions. Avoid direct sunlight and heat. The gloves are packed in dispenser suitable for transportation. Keep the gloves in the box when they are not in use.

7) Instruction for Use

a) For maximum comfort, choose the fitting gloves size for your hands.
As examination gloves are ambidextrous, it should be donned according to the correct hand-side as indicated on the inner wrapper.

b) Donning:
- Prior to donning, perform hand hygiene using hand scrub or antimicrobial solution and water.

c) 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 or non-sterile surface.

d) Doffing – Hold glove bead and pull toward the finger until the glove come off

e) These gloves have not been tested against chemotherapy drugs.

8) Precaution for disposal

Dispose of soiled examination gloves in accordance with relevant regulations that practice safe disposal of clinical waste.