



Document Number : INTCO-CE-DC-SPVC-001

Version: A/0

EU DECLARATION OF CONFORMITY

Manufacturer

Authorized Representative

Name: **Shandong Intco Medical Products Co., Ltd.**

Name: **Lotus NL B.V.**

Address: **Qiwang Road NO.9888, Naoshan Industrial Park, Qingzhou, Shandong, China**

Address: **Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands**

Declares that the MDR described hereafter

Product name and model:

SYNGUARD® Vinyl Exam Gloves

EMDN code: T01020201

Model:

XS IN005EUa/b/c

S IN001EUa/b/c/d

M IN002EUa/b/c/d

L IN003EUa/b/c/d

XL IN004EUa/b/c

Product Code: SVV/B/H/PE (Please refer to the attachment for more details).

Basic UDI-DI: 697024575Vinyl85

This Declaration of Conformity is issued under the sole responsibility of the manufacturer:

Shandong Intco Medical Products Co., Ltd.

SRN: CN-MF-000002100

Classification: Class I for medical device(rule 1 & rule 5, Annex VIII MDR), Cat III for PPE

We declare that the production of medical devices as specified above is carried out in accordance with MDR EU 2017/745 and PPE regulation EU 2016/425

MDR Harmonized Standard: EN ISO 13485:2016; EN 14971:2019; EN 1041:2008; EN 15223-1:2016; EN 455-1:2020; EN 455-2:2015; EN 455-3:2015; EN 455-4:2009; ISO 10993-1:2018; ISO 10993-10:2010. ISO 10993-5:2009.

PPE Harmonized Standard: EN ISO 21420:2020, EN ISO 374-1:2016 +A1:2018, EN374-4:2014, EN ISO 374-5:2016

The notified body SATRA Technology Europe Ltd (Number: 2777) performed:

- EU type-examination Certificate (Module B), certificate number: 2777/11030-04/E00-00
- Module C2 certificate

We agree to develop, implement and maintain a documented post-production monitoring process.

Shandong 2021-06-12

Place , date

Rick Cheng Quality Manager

Legally binding signature, Function

Attached: Product code

color	Size / Product code					
	XS	S	M	L	XL	XXL
Clear	SVV/B/H/PE10003	SVV/B/H/PE10004	SVV/B/H/PE10005	SVV/B/H/PE10006	SVV/B/H/PE10007	SVV/B/H/PE10008
	SVV/B/H/PE15003	SVV/B/H/PE15004	SVV/B/H/PE15005	SVV/B/H/PE15006	SVV/B/H/PE15007	SVV/B/H/PE15008
Blue	SVV/B/H/PE10013	SVV/B/H/PE10014	SVV/B/H/PE10015	SVV/B/H/PE10016	SVV/B/H/PE10017	SVV/B/H/PE10018
	SVV/B/H/PE15013	SVV/B/H/PE15014	SVV/B/H/PE15015	SVV/B/H/PE15016	SVV/B/H/PE15017	SVV/B/H/PE15018
White	SVV/B/H/PE10023	SVV/B/H/PE10024	SVV/B/H/PE10025	SVV/B/H/PE10026	SVV/B/H/PE10027	SVV/B/H/PE10028
	SVV/B/H/PE15023	SVV/B/H/PE15024	SVV/B/H/PE15025	SVV/B/H/PE15026	SVV/B/H/PE15027	SVV/B/H/PE15028
Yellow	SVV/B/H/PE10063	SVV/B/H/PE10064	SVV/B/H/PE10065	SVV/B/H/PE10066	SVV/B/H/PE10067	SVV/B/H/PE10068
	SVV/B/H/PE15063	SVV/B/H/PE15064	SVV/B/H/PE15065	SVV/B/H/PE15066	SVV/B/H/PE15067	SVV/B/H/PE15068



Dokumentnummer : INTCO-CE-DC-SPVC-001

Version: A/0

EU-FÖRSÄKRAN OM ÖVERENSSTÄMMELSE

Tillverkare

Auktoriserad representant

Namn: Shandong Intco Medical Products Co., Ltd.
Postadress: Qiwang Road NO.9888, Naoshan Industrial Park, Qingzhou, Shandong, China

Namn: Lotus NL B.V.

Postadress: Koningin Julianaplein 10, 1e Verd, 2595AA , The Hague , Netherlands

Försäkrar att den MDR som beskrivs nedan

Produktnamn och modell:

SYNGUARD® Vinyl Exam Gloves

EMDN-kod: T01020201

Modell:

XS IN005EUa/b/c
S IN001EUa/b/c/d
M IN002EUa/b/c/d
L IN003EUa/b/c/d
XL IN004EUa/b/c

Produktkod: SVV/B/H/PE (se bilaga för mer information).

Grundläggande UDI-DI: 697024575Vinyl85

Denna försäkran om överensstämmelse utfärdas på tillverkarens eget ansvar: **Shandong Intco Medical Products Co., Ltd.**

SRN: CN-MF-000002100

Klassificering: Klass I för medicintekniska produkter (regel 1 och regel 5, bilaga VIII MDR), kat. III för personlig skyddsutrustning (PPE)

Vi försäkrar att tillverkningen av medicintekniska produkter enligt ovan utförs i enlighet med MDR EU 2017/745 och PPE EU 2016/425

Harmoniserad standard för MDR: EN ISO 13485:2016; EN 14971:2019; EN 1041:2008; EN 15223-1:2016; EN 455-1:2020; EN 455-2:2015; EN 455-3:2015; EN 455-4:2009; ISO 10993-1:2018; ISO 10993-10:2010. ISO 10993-5:2009.

Harmoniserad standard för personlig skyddsutrustning: EN ISO 21420:2020. EN ISO 374-1:2016 +A1:2018. EN374-4:2014. EN ISO 374-5:2016

Det anmälda organet SATRA Technology Europe Ltd (nummer: 2777) har utfört:

- EU-typkontroll, certifikat (modul B), certifikatnummer: 2777/11030-04/E00-00

- Modul C2-certifikat

Vi kommer överens om att utveckla, implementera och upprätthålla en dokumenterad process för övervakning efter produktion.

Shandong 2021-06-12

Ort , datum

Rick Cheng Quality Manager

Juridiskt bindande underskrift, Befattning

Rick Cheng

Bifogat: Produktkod

färg	Storlek/artikelnummer					
	XS	S	M	L	XL	XXL
Transparent	SVV/B/H/PE10003	SVV/B/H/PE10004	SVV/B/H/PE10005	SVV/B/H/PE10006	SVV/B/H/PE10007	SVV/B/H/PE10008
	SVV/B/H/PE15003	SVV/B/H/PE15004	SVV/B/H/PE15005	SVV/B/H/PE15006	SVV/B/H/PE15007	SVV/B/H/PE15008
	SVV/B/H/PE10013	SVV/B/H/PE10014	SVV/B/H/PE10015	SVV/B/H/PE10016	SVV/B/H/PE10017	SVV/B/H/PE10018
Blå	SVV/B/H/PE15013	SVV/B/H/PE15014	SVV/B/H/PE15015	SVV/B/H/PE15016	SVV/B/H/PE15017	SVV/B/H/PE15018
	SVV/B/H/PE10023	SVV/B/H/PE10024	SVV/B/H/PE10025	SVV/B/H/PE10026	SVV/B/H/PE10027	SVV/B/H/PE10028
Vit	SVV/B/H/PE15023	SVV/B/H/PE15024	SVV/B/H/PE15025	SVV/B/H/PE15026	SVV/B/H/PE15027	SVV/B/H/PE15028
	SVV/B/H/PE10063	SVV/B/H/PE10064	SVV/B/H/PE10065	SVV/B/H/PE10066	SVV/B/H/PE10067	SVV/B/H/PE10068
Gul	SVV/B/H/PE15063	SVV/B/H/PE15064	SVV/B/H/PE15065	SVV/B/H/PE15066	SVV/B/H/PE15067	SVV/B/H/PE15068



Številka dokumenta: INTCO-CE-DC-SPVC-001

Različica: A/0

IZJAVA EU O SKLADNOSTI

Proizvajalec

Ime: Shandong Intco Medical Products Co., Ltd.

Naslov: Qiwang Road NO.9888,
Naoshan Industrial Park, Qingzhou,
Shandong, Kitajska

Pooblaščen zastopnik

Ime: Lotus NL B.V.

Naslov: Koningin Julianaplein 10, 1e
Verd, 2595AA, The Hague, Nizozemska

Izjavlja, da je MDR, opisan v nadaljevanju

Ime in model izdelka:

Rokavice za pregled iz vinila SYNGUARD®

Oznaka EMDN: T01020201

Model:

XS IN005EUa/b/c

S IN001EUa/b/c/d

M IN002EUa/b/c/d

L IN003EUa/b/c/d

XL IN004EUa/b/c

Oznaka izdelka: SVV/B/H/PE (preverite prilogo za več podrobnosti).

Osnovni UDI-DI: 697024575Viny185

Za izdajo te izjave o skladnosti je odgovoren izključno proizvajalec: **Shandong Intco Medical Products Co., Ltd.**

SRN: CN-MF-000002100

Razred: razred I za medicinske pripomočke (pravilo 1 in pravilo 5, Priloga VIII MDR), kategorija III za osebno varovalno opremo.

Izjavljamo, da proizvodnja medicinskih pripomočkov, navedenih zgoraj, poteka v skladu z uredbo MDR EU 2017/745 in uredbo EU 2016/425 o osebni varovalni opremi.

Harmonizirani standard MDR: EN ISO 13485:2016; EN 14971:2019; EN 1041:2008; EN 15223-1:2016; EN 455-1:2020; EN 455-2:2015; EN 455-3:2015; EN 455-4:2009; ISO 10993-1:2018; ISO 10993-10:2010. ISO 10993-5:2009.

Harmonizirani standard PPE: EN ISO 21420:2020, EN ISO 374-1:2016 +A1:2018, EN374-4:2014, EN ISO 374-5:2016

Priglašeni organ SATRA Technology Europe Ltd (številka: 2777) je opravil:

- certifikat o EU-pregledu tipa (Modul B), številka certifikata: 2777/11030-04/E00-00,
- certifikat Modul 2.

Potrjujemo, da bomo razvili, izvajali in vzdrževali dokumentiran postopek spremljanja po izdelavi.

Shandong, 12. 6. 2021

Kraj, datum

vodja kakovosti: Rick Cheng

Pravno zavezujoč podpis, funkcija

Rick Cheng

Priloga: Oznaka izdelka

Barva	Velikost/oznaka izdelka					
	XS	S	M	L	XL	XXL
Prosojna	SVV/B/H/PE10003	SVV/B/H/PE10004	SVV/B/H/PE10005	SVV/B/H/PE10006	SVV/B/H/PE10007	SVV/B/H/PE10008
	SVV/B/H/PE15003	SVV/B/H/PE15004	SVV/B/H/PE15005	SVV/B/H/PE15006	SVV/B/H/PE15007	SVV/B/H/PE15008
	SVV/B/H/PE10013	SVV/B/H/PE10014	SVV/B/H/PE10015	SVV/B/H/PE10016	SVV/B/H/PE10017	SVV/B/H/PE10018
Modra	SVV/B/H/PE15013	SVV/B/H/PE15014	SVV/B/H/PE15015	SVV/B/H/PE15016	SVV/B/H/PE15017	SVV/B/H/PE15018
	SVV/B/H/PE10023	SVV/B/H/PE10024	SVV/B/H/PE10025	SVV/B/H/PE10026	SVV/B/H/PE10027	SVV/B/H/PE10028
	SVV/B/H/PE15023	SVV/B/H/PE15024	SVV/B/H/PE15025	SVV/B/H/PE15026	SVV/B/H/PE15027	SVV/B/H/PE15028
Bela	SVV/B/H/PE10063	SVV/B/H/PE10064	SVV/B/H/PE10065	SVV/B/H/PE10066	SVV/B/H/PE10067	SVV/B/H/PE10068
	SVV/B/H/PE15063	SVV/B/H/PE15064	SVV/B/H/PE15065	SVV/B/H/PE15066	SVV/B/H/PE15067	SVV/B/H/PE15068
	SVV/B/H/PE10063	SVV/B/H/PE10064	SVV/B/H/PE10065	SVV/B/H/PE10066	SVV/B/H/PE10067	SVV/B/H/PE10068



Dokumentnummer :INTCO-CE-DC-SPVC-001

Versjon: A/0

EU-SAMSVARSERKLÆRING

Produsent

Autorisert representant

Navn: Shandong Intco Medical Products Co., Ltd.

Navn: Lotus NL B.V.

**Adresse: Qiwang Road NO.9888,
Naoshan Industrial Park, Qingzhou,
Shandong, Kina**

**Adresse: Koningin Julianaplein 10, 1e
Verd, 2595AA, Haag, Nederland**

Erklærer at det medisinske utstyret som er beskrevet nedenfor

Produktnavn og modell:

SYNGUARD® vinyl undersøkelseshansker

EMDN-kode: T01020201

Modell:

XS IN005EUa/b/c

S IN001EUa/b/c/d

M IN002EUa/b/c/d

L IN003EUa/b/c/d

XL IN004EUa/b/c

Produktkode: SVV/B/H/PE (Se mer informasjon i vedlegget).

Grunnleggende UDI-DI: 697024575Vinyl85

Denne samsvarserklæringen er utstedt på produsentens eneansvar: **Shandong Intco Medical Products Co., Ltd.**

SRN: CN-MF-000002100

Klassifisering: Klasse I for medisinsk utstyr (regel 1 og regel 5, tillegg VIII MDR), kategori III for PVU

Vi erklærer at produksjonen av det medisinske utstyret som er spesifisert ovenfor, er utført i samsvar med forordningen om medisinsk utstyr EU 2017/745 og PVU-forordningen EU 2016/425

Harmonisert standard for medisinsk utstyr: EN ISO 13485:2016; EN 14971:2019; EN 1041:2008; EN 15223-1:2016; EN 455-1:2020; EN 455-2:2015; EN 455-3:2015; EN 455-4:2009; ISO 10993-1:2018; ISO 10993-10:2010. ISO 10993-5:2009.

Harmonisert PVU-standard: EN ISO 21420:2020, EN ISO 374-1:2016 +A1:2018, EN374-4:2014, EN ISO 374-5:2016

Det tekniske kontrollorganet SATRA Technology Europe Ltd (nummer: 2777) har utført:

- EU-typegodkjenningssertifikat (modul B), sertifikatnummer: 2777/11030-04/E00-00

- Modul C2-sertifikat

Vi godtar å utvikle, implementere og vedlikeholde en dokumentert overvåkningsprosess etter produksjon.

Shandong 12.06.2021

Sted, dato

Rick Cheng, Quality Manager

Juridisk bindende signatur, Funksjon

Handwritten signature of Rick Cheng in black ink, written in a cursive style.

Vedlegg: Produktkode

farge	Størrelse/produktkode					
	XS	S	M	L	XL	XXL
Klar	SVV/B/H/PE10003	SVV/B/H/PE10004	SVV/B/H/PE10005	SVV/B/H/PE10006	SVV/B/H/PE10007	SVV/B/H/PE10008
	SVV/B/H/PE15003	SVV/B/H/PE15004	SVV/B/H/PE15005	SVV/B/H/PE15006	SVV/B/H/PE15007	SVV/B/H/PE15008
Blå	SVV/B/H/PE10013	SVV/B/H/PE10014	SVV/B/H/PE10015	SVV/B/H/PE10016	SVV/B/H/PE10017	SVV/B/H/PE10018
	SVV/B/H/PE15013	SVV/B/H/PE15014	SVV/B/H/PE15015	SVV/B/H/PE15016	SVV/B/H/PE15017	SVV/B/H/PE15018
Hvit	SVV/B/H/PE10023	SVV/B/H/PE10024	SVV/B/H/PE10025	SVV/B/H/PE10026	SVV/B/H/PE10027	SVV/B/H/PE10028
	SVV/B/H/PE15023	SVV/B/H/PE15024	SVV/B/H/PE15025	SVV/B/H/PE15026	SVV/B/H/PE15027	SVV/B/H/PE15028
Gul	SVV/B/H/PE10063	SVV/B/H/PE10064	SVV/B/H/PE10065	SVV/B/H/PE10066	SVV/B/H/PE10067	SVV/B/H/PE10068
	SVV/B/H/PE15063	SVV/B/H/PE15064	SVV/B/H/PE15065	SVV/B/H/PE15066	SVV/B/H/PE15067	SVV/B/H/PE15068



Documentnummer:INTCO-CE-DC-SPVC-001

Versie: A/0

EU-CONFORMITEITSVERKLARING

Fabrikant

Naam: Shandong Intco Medical Products Co., Ltd.
Adres: Qiwang Road NO.9888, Naoshan Industrial Park, Qingzhou, Shandong, China

Gemachtigde

Naam: Lotus NL B.V.
Adres: Koningin Julianaplein 10, 1e Verd, 2595 AA, Den Haag, Nederland

Verklaart dat de hierna beschreven MDR

Productnaam en model:

SYNGUARD® vinyl onderzoekshandschoenen

EMDN code: T01020201

Model:

XS IN005EUa/b/c
S IN001EUa/b/c/d
M IN002EUa/b/c/d
L IN003EUa/b/c/d
XL IN004EUa/b/c

Productcode: SVV/B/H/PE (zie de bijlage voor meer informatie).

Basis UDI-DI: 697024575Vinyl85

Deze conformiteitsverklaring wordt verstrekt onder volledige verantwoordelijkheid van de fabrikant: **Shandong Intco Medical Products Ltd.**

SRN: CN-MF-000002100

Classificatie: Klasse I voor medische hulpmiddelen (voorschrift 1 & regel 5, bijlage VIII MDR), categorie III voor PBM

Wij verklaren dat de productie van medische hulpmiddelen zoals hierboven gespecificeerd wordt uitgevoerd in overeenstemming met MDR EU 2017/745 en PBM-verordening EU 2016/425.

Geharmoniseerde MDR-norm: EN ISO 13485:2016; EN 14971:2019; EN 1041:2008; EN 15223-1:2016; EN 455-1:2020; EN 455-2:2015; EN 455-3:2015; EN 455-4:2009; ISO 10993-1:2018; ISO 10993-10:2010. ISO 10993-5:2009.

Geharmoniseerde PBM-norm: EN ISO 21420:2020, EN ISO 374-1:2016 +A1:2018, EN374-4:2014, EN ISO 374-5:2016

De aangemelde instantie SATRA Technology Europe Ltd (nummer: 2777) heeft het volgende uitgevoerd:

- Certificaat van EU-typeonderzoek (module B), certificaatnummer: 2777/11030-04/E00-00
- Certificaat module C2

We stemmen ermee in om na de productie een gedocumenteerd controleproces te ontwikkelen, implementeren en onderhouden.

Shandong 2021-06-12

Plaats, datum Wettelijk bindende handtekening, functie

Rick Cheng Quality Manager

Rick Cheng

Bijgevoegd: Productcode

kleur	Maat/productcode					
	XS	S	M	L	XL	XXL
Transparant	SVV/B/H/PE10003	SVV/B/H/PE10004	SVV/B/H/PE10005	SVV/B/H/PE10006	SVV/B/H/PE10007	SVV/B/H/PE10008
	SVV/B/H/PE15003	SVV/B/H/PE15004	SVV/B/H/PE15005	SVV/B/H/PE15006	SVV/B/H/PE15007	SVV/B/H/PE15008
Blauw	SVV/B/H/PE10013	SVV/B/H/PE10014	SVV/B/H/PE10015	SVV/B/H/PE10016	SVV/B/H/PE10017	SVV/B/H/PE10018
	SVV/B/H/PE15013	SVV/B/H/PE15014	SVV/B/H/PE15015	SVV/B/H/PE15016	SVV/B/H/PE15017	SVV/B/H/PE15018
Wit	SVV/B/H/PE10023	SVV/B/H/PE10024	SVV/B/H/PE10025	SVV/B/H/PE10026	SVV/B/H/PE10027	SVV/B/H/PE10028
	SVV/B/H/PE15023	SVV/B/H/PE15024	SVV/B/H/PE15025	SVV/B/H/PE15026	SVV/B/H/PE15027	SVV/B/H/PE15028
Geel	SVV/B/H/PE10063	SVV/B/H/PE10064	SVV/B/H/PE10065	SVV/B/H/PE10066	SVV/B/H/PE10067	SVV/B/H/PE10068
	SVV/B/H/PE15063	SVV/B/H/PE15064	SVV/B/H/PE15065	SVV/B/H/PE15066	SVV/B/H/PE15067	SVV/B/H/PE15068



Numero documento : INTCO-CE-DC-SPVC-001

Versione: A/0

DICHIARAZIONE DI CONFORMITÀ UE

Fabbricante

Nome: Shandong Intco Medical Products Co. Ltd.
Indirizzo: Qiwang Road NO.9888, Naoshan Industrial Park, Qingzhou, Shandong, Cina

Rappresentante autorizzato

Nome: Lotus NL B.V.
Indirizzo: Koningin Julianaplein 10, 1e Verd, 2595AA, L'Aia, Paesi Bassi

Dichiara che l'MDR descritto di seguito

Nome prodotto e modello:

Guanti da esame in vinile SYNGUARD®

EMDN code: T01020201

Modello:

XS IN005EUa/b/c
S IN001EUa/b/c/d
M IN002EUa/b/c/d
L IN003EUa/b/c/d
XL IN004EUa/b/c

Codice prodotto: SVV/B/H/PE (per ulteriori dettagli, fare riferimento all'allegato).

UDI-DI di base: 697024575Viny185

La presente dichiarazione di conformità è rilasciata sotto la responsabilità esclusiva del produttore: **Shandong Intco Medical Products Co., Ltd.**

SRN: CN-MF-000002100

Classificazione: Classe I dei dispositivi medici (regola 1 e regola 5, Allegato VIII MDR), Cat III per DPI

Dichiariamo che la produzione dei dispositivi medici come sopra specificato è effettuata in conformità al Regolamento MDR EU 2017/745 e al Regolamento DPI EU 2016/425

Standard armonizzato MDR: EN ISO 13485:2016; EN 14971:2019; EN 1041:2008; EN 15223-1:2016; EN 455-1:2020; EN 455-2:2015; EN 455-3:2015; EN 455-4:2009; ISO 10993-1:2018; ISO 10993-10:2010. ISO 10993-5:2009.

Standard armonizzato DPI: EN ISO 21420:2020, EN ISO 374-1:2016 +A1:2018, EN374-4:2014, EN ISO 374-5:2016

L'organismo notificato SATRA Technology Europe Ltd (numero: 2777) ha eseguito:

- Certificato di esame di tipo UE (Modulo B), numero certificato: 2777/11030-04/E00-00

- Certificato Modulo C2

Accettiamo di sviluppare, implementare e mantenere un processo di monitoraggio post-produzione documentato.

Shandong 2021-06-12

Luogo, data

Rick Cheng Quality Manager

Firma legalmente vincolante, Funzione

Rick Cheng

Allegato: Codice prodotto

Dimensioni/Codice prodotto						
colore	XS	S	M	L	XL	XXL
Trasparente	SVV/B/H/PE10003	SVV/B/H/PE10004	SVV/B/H/PE10005	SVV/B/H/PE10006	SVV/B/H/PE10007	SVV/B/H/PE10008
	SVV/B/H/PE15003	SVV/B/H/PE15004	SVV/B/H/PE15005	SVV/B/H/PE15006	SVV/B/H/PE15007	SVV/B/H/PE15008
Blu	SVV/B/H/PE10013	SVV/B/H/PE10014	SVV/B/H/PE10015	SVV/B/H/PE10016	SVV/B/H/PE10017	SVV/B/H/PE10018
	SVV/B/H/PE15013	SVV/B/H/PE15014	SVV/B/H/PE15015	SVV/B/H/PE15016	SVV/B/H/PE15017	SVV/B/H/PE15018
Bianco	SVV/B/H/PE10023	SVV/B/H/PE10024	SVV/B/H/PE10025	SVV/B/H/PE10026	SVV/B/H/PE10027	SVV/B/H/PE10028
	SVV/B/H/PE15023	SVV/B/H/PE15024	SVV/B/H/PE15025	SVV/B/H/PE15026	SVV/B/H/PE15027	SVV/B/H/PE15028
Giallo	SVV/B/H/PE10063	SVV/B/H/PE10064	SVV/B/H/PE10065	SVV/B/H/PE10066	SVV/B/H/PE10067	SVV/B/H/PE10068
	SVV/B/H/PE15063	SVV/B/H/PE15064	SVV/B/H/PE15065	SVV/B/H/PE15066	SVV/B/H/PE15067	SVV/B/H/PE15068