

EN - Gloves are designed to protect the hands mainly from chemical splash risks and comply with the harmonised standards shown by pictograms. Explanation of symbols & pictograms:
CE XXXX - Product is certified in accordance to the requirements of the European Regulation 2016/425...

ANSELL SINGLE USE GLOVES - CAT. III

- EN ISO 374-2016: Type C - Protection against chemical splash risks...
EN ISO 374-2016: Type C - Protection against chemical splash risks...
EN ISO 374-2016: Type C - Protection against chemical splash risks...

CE&DI 31 Languages

For more information, visit: www.ansell.com
Warning! Chemical resistance data has been assessed under laboratory conditions from samples taken from the palm side of the glove...
EN ISO 374-2016: Type C - Protection against chemical splash risks...
EN ISO 374-2016: Type C - Protection against chemical splash risks...

Ansell Healthcare Europe NV
Riverside Business Park
BVD International, 55
1070 Brussels, Belgium
+32 2 528 74 00

Instructions for use 02/19

ANSELL SINGLE USE GLOVES - CAT. III EN

A. Utilização - as luvas foram concebidas para proteger as mãos principalmente de riscos de salpicos de produtos químicos e cumprir as normas harmonizadas indicadas mediante pictogramas. Explicação dos símbolos e pictogramas:

- CE XXXX - Produto está certificado em conformidade com os requisitos do Regulamento (UE) 2016/425...
EN ISO 374-2016: Type C - Protection against chemical splash risks...
EN ISO 374-2016: Type C - Protection against chemical splash risks...

ANSELL SINGLE USE GLOVES - CAT. III EN

EN ISO 374-2016: Type C - Protection against chemical splash risks...
EN ISO 374-2016: Type C - Protection against chemical splash risks...
EN ISO 374-2016: Type C - Protection against chemical splash risks...

EN - The gloves are designed for protection as follows: mainly from the risks of splashes of products and comply with the harmonized standards indicated by pictograms. Explicación de los símbolos y pictogramas:

GUANTES MONOUSO ANSELL - CAT. III ES

- CE XXXX - Este producto cumple con los requisitos del Reglamento Europeo 2016/425...
EN ISO 374-2016: Type C - Protection against chemical splash risks...
EN ISO 374-2016: Type C - Protection against chemical splash risks...

ANSELL MONOUSO ANSELL - CAT. III ES

EN ISO 374-2016: Type C - Protection against chemical splash risks...
EN ISO 374-2016: Type C - Protection against chemical splash risks...
EN ISO 374-2016: Type C - Protection against chemical splash risks...

ANSELL MONOUSO ANSELL - CAT. III ES

EN ISO 374-2016: Type C - Protection against chemical splash risks...
EN ISO 374-2016: Type C - Protection against chemical splash risks...
EN ISO 374-2016: Type C - Protection against chemical splash risks...

EN - Questi guanti sono destinati a proteggere le mani principalmente dai rischi chimici e sono conformi alle norme armonizzate mostrate dai pittogrammi. Spiegazione dei simboli e pittogrammi:

GUANTI MONOUSO ANSELL - CAT. III IT

- CE XXXX - Il prodotto è conforme e certificato in base ai requisiti del regolamento europeo 2016/425...
EN ISO 374-2016: Type C - Protection against chemical splash risks...
EN ISO 374-2016: Type C - Protection against chemical splash risks...

ANSELL-HANDSCHEN VOOR EENMALIG GEBRUIK - CAT. III NL

EN ISO 374-2016: Type C - Protection against chemical splash risks...
EN ISO 374-2016: Type C - Protection against chemical splash risks...
EN ISO 374-2016: Type C - Protection against chemical splash risks...

ANSELL-HANDSCHEN VOOR EENMALIG GEBRUIK - CAT. III NL

EN ISO 374-2016: Type C - Protection against chemical splash risks...
EN ISO 374-2016: Type C - Protection against chemical splash risks...
EN ISO 374-2016: Type C - Protection against chemical splash risks...

EN - Deze handschoen zijn ontworpen om handen hoofdzakelijk tegen splashes van chemicaliën te beschermen en voldoen aan de geharmoniseerde normen aangegeven door de pictogrammen. Uitleg over symbolen & pictogrammen:

ANSELL-ENGANGSHANDSKER - KAT. III DA

- CE XXXX - Produktet er certificeret i overensstemmelse med kravene i den europæiske forordning 2016/425...
EN ISO 374-2016: Type C - Protection against chemical splash risks...
EN ISO 374-2016: Type C - Protection against chemical splash risks...

ANSELL-ENGANGSHANDSKER - KAT. III DA

EN ISO 374-2016: Type C - Protection against chemical splash risks...
EN ISO 374-2016: Type C - Protection against chemical splash risks...
EN ISO 374-2016: Type C - Protection against chemical splash risks...

ANSELL-ENGANGSHANDSKER - KAT. III DA

EN ISO 374-2016: Type C - Protection against chemical splash risks...
EN ISO 374-2016: Type C - Protection against chemical splash risks...
EN ISO 374-2016: Type C - Protection against chemical splash risks...

EN - Handikere er beregnet som beskyttelse for hændene, hovedsageligt mod sprøjt for kemikalier og overholder harmoniserede standarder som vist på pictogrammer. Forklaring på symboler og pictogrammer:

ANSELL-ENGANGSHANDSKER - KAT. III NO

- CE XXXX - Produktet er sertifisert i overensstemmelse med kravene i den europeiske forordning 2016/425...
EN ISO 374-2016: Type C - Protection against chemical splash risks...
EN ISO 374-2016: Type C - Protection against chemical splash risks...

ANSELL-ENGANGSHANDSKER - KAT. III NO

EN ISO 374-2016: Type C - Protection against chemical splash risks...
EN ISO 374-2016: Type C - Protection against chemical splash risks...
EN ISO 374-2016: Type C - Protection against chemical splash risks...

ANSELL-ENGANGSHANDSKER - KAT. III NO

EN ISO 374-2016: Type C - Protection against chemical splash risks...
EN ISO 374-2016: Type C - Protection against chemical splash risks...
EN ISO 374-2016: Type C - Protection against chemical splash risks...

EN - Les gants sont destinés essentiellement pour protéger les mains contre les risques de projections chimiques et respectent les normes harmonisées illustrées par des pictogrammes. Explication des symboles et pictogrammes:

GANTS À USAGE UNIQUE ANSELL - CAT. III FR

- CE XXXX - Le produit est certifié en conformité avec les dispositions du Règlement européen 2016/425...
EN ISO 374-2016: Type C - Protection against chemical splash risks...
EN ISO 374-2016: Type C - Protection against chemical splash risks...

ANSELL SINGLE USE GLOVES - CAT. III EN

EN ISO 374-2016: Type C - Protection against chemical splash risks...
EN ISO 374-2016: Type C - Protection against chemical splash risks...
EN ISO 374-2016: Type C - Protection against chemical splash risks...

ANSELL SINGLE USE GLOVES - CAT. III EN

EN ISO 374-2016: Type C - Protection against chemical splash risks...
EN ISO 374-2016: Type C - Protection against chemical splash risks...
EN ISO 374-2016: Type C - Protection against chemical splash risks...

EN - Die Handschuhe sind für den Schutz der Hände vorverpackung über Chemikalienprojektion bestimmt und entsprechen den harmonisierten Normen gemäß den auf der Verpackung angegebenen Piktogrammen. Erläuterung der Symbole und Piktogramme:

EINMALHANDSCHUHE VON ANSELL - KAT. III DE

- CE XXXX - Produkt erfüllt die Anforderungen der Verordnung (EU) 2016/425 und ist entsprechend zertifiziert...
EN ISO 374-2016: Type C - Protection against chemical splash risks...
EN ISO 374-2016: Type C - Protection against chemical splash risks...

ANSELL SINGLE USE GLOVES - CAT. III EN

EN ISO 374-2016: Type C - Protection against chemical splash risks...
EN ISO 374-2016: Type C - Protection against chemical splash risks...
EN ISO 374-2016: Type C - Protection against chemical splash risks...

ANSELL SINGLE USE GLOVES - CAT. III EN

EN ISO 374-2016: Type C - Protection against chemical splash risks...
EN ISO 374-2016: Type C - Protection against chemical splash risks...
EN ISO 374-2016: Type C - Protection against chemical splash risks...

EN - Die Handschuhe sind für den Schutz der Hände vorverpackung über Chemikalienprojektion bestimmt und entsprechen den harmonisierten Normen gemäß den auf der Verpackung angegebenen Piktogrammen. Erläuterung der Symbole und Piktogramme:

EINMALHANDSCHUHE VON ANSELL - KAT. III DE

- CE XXXX - Produkt erfüllt die Anforderungen der Verordnung (EU) 2016/425 und ist entsprechend zertifiziert...
EN ISO 374-2016: Type C - Protection against chemical splash risks...
EN ISO 374-2016: Type C - Protection against chemical splash risks...

ANSELL SINGLE USE GLOVES - CAT. III EN

EN ISO 374-2016: Type C - Protection against chemical splash risks...
EN ISO 374-2016: Type C - Protection against chemical splash risks...
EN ISO 374-2016: Type C - Protection against chemical splash risks...

ANSELL SINGLE USE GLOVES - CAT. III EN

EN ISO 374-2016: Type C - Protection against chemical splash risks...
EN ISO 374-2016: Type C - Protection against chemical splash risks...
EN ISO 374-2016: Type C - Protection against chemical splash risks...

REKAWIJE JEDNORAZOWE ANSELL — KAT. III PL

A. Zastosowanie — Rękawice to przeznaczone do ochrony przed chemicznymi czynnikami i innymi czynnikami...
CE XXXX — Produkt jest zgodny z dyrektywą certyfikacji Europejskiej...
EN ISO 374-2:2016 / A / B / C / D E — Ocena przed zagrożeniami chemicznymi...

Świadectwo badania typu UE (moduł B) wydane przez: Centebel Belgium (ID: 0493), Technologiczny 7, 8-9052 Zwiande.
Ostrzeżenie! Działanie chemiczne...
EN ISO 374-2:2016 / Type A, B, C / K / L / O P S / M — Ocena przed zagrożeniami chemicznymi...

РЪКAVИЦИ ЗА ЕДНОКРАТНА УПРЕТБА ОТ ANSELL — KAT. III BG

A. Употреба — Ръкавиците се предназначават за защита на ръцете от химични вещества...
CE XXXX — Продуктът отговаря на изискванията на Регламента UE (2016/425)...
EN ISO 374-2:2016 / A / B / C / D E — Оценка на риска от химични вещества...

Съответствие на CE за изпитване на типа (modul B) от Centebel Belgium (ID: 0493), Technologiczny 7, 8-9052 Zwiande.
Предупреждение! Движение на химично вещество...
EN ISO 374-2:2016 / Type A, B, C / K / L / O P S / M — Оценка на риска от химични вещества...

ROKAVICE ANSELL ZA ENKRATNO UPORABO — III. KATEGORIJE SL

A. Uporaba — Rokavice so namenjene za zaščito pred kemikalijami...
CE XXXX — Izdelek je skladen s predpisi Evropske unije...
EN ISO 374-2:2016 / A / B / C / D E — Ocena pred kemijskimi nevarnostmi...

Področje certifikacije skladno z veljavno zakonodajo...
EN ISO 374-2:2016 / Type A, B, C / K / L / O P S / M — Ocena pred kemijskimi nevarnostmi...

ANSELLI ÜHEKORDSELT KASUTATAVA KINDAD — III. KATEGORIA ET

A. Kasutamise — Kindad on mõeldud kaitsa keemiliste ainetega...
CE XXXX — Toode vastab Euroopa Liidu nõuetele...
EN ISO 374-2:2016 / A / B / C / D E — Riski hindamine...

En ISO 374-2:2016 / Type A, B, C / K / L / O P S / M — Ocena pred kemijskimi nevarnostmi...

„ANSELL“ VIENKARTINESIS PIRŠTINES — III KAT. LT

A. Naudojimas — Pirštinės yra sukurta apsaugoti rankas...
CE XXXX — Gaminys atitinka Europos Sąjungos reikalavimus...
EN ISO 374-2:2016 / A / B / C / D E — Riskų vertinimas...

EN ISO 374-2:2016 / Type A, B, C / K / L / O P S / M — Ocena pred kemijskimi nevarnostmi...

INGWANTEN ANSELL BI JINTUŻAW DARBA BISS — KAT. III MT

A. Uża — Inġenanti huma mibruha biex jiprotteġu idij...
CE XXXX — Il-prodott hu konformi cċertifikat skanti...
EN ISO 374-2:2016 / A / B / C / D E — Valutazzjoni ta' riskju...

EN ISO 374-2:2016 / Type A, B, C / K / L / O P S / M — Ocena pred kemijskimi nevarnostmi...

MANŠINI ANSELL DE UNICA FOLOSINȚĂ — CAT. III RO

A. Utilizare — Mănușile sunt destinate protejării mâinilor...
CE XXXX — Produsul este conceput pentru a proteja mâinile...
EN ISO 374-2:2016 / A / B / C / D E — Evaluarea riscului...

EN ISO 374-2:2016 / Type A, B, C / K / L / O P S / M — Ocena pred kemijskimi nevarnostmi...

JEDNORAZOVÉ RUKAVICE ANSELL — KAT. III SK

A. Použitvanie — Rukavice sú určené na ochranu rúk...
CE XXXX — Výrobok certyfikovaný podľa požiadaviek...
EN ISO 374-2:2016 / A / B / C / D E — Hodnotenie rizika...

EN ISO 374-2:2016 / Type A, B, C / K / L / O P S / M — Ocena pred kemijskimi nevarnostmi...

LÁMHAINNÍ ÁRÓN USÓYSE ANSELL — CAT. III GA

A. Úsáid — Lámhainníní ceaptha chun na lámha a chosaint...
CE XXXX — Comhábhan an táirce comptaí...
EN ISO 374-2:2016 / A / B / C / D E — Rátaid na riosca...

EN ISO 374-2:2016 / Type A, B, C / K / L / O P S / M — Ocena pred kemijskimi nevarnostmi...

JEDNOKRATNE RUKAVICE ANSELL — KAT. III HR

Uporaba: rukavice su osmišljene za zaštitu ruku...
CE XXXX — Proizvod je certifikiran u skladu sa zahtjevima...
EN ISO 374-2:2016 / A / B / C / D E — Procjena rizika...

EN ISO 374-2:2016 / Type A, B, C / K / L / O P S / M — Ocena pred kemijskimi nevarnostmi...

ANSELL TEK KULLANIMLIK ELDIVLERIN — KAT. III TR

A. Kullanım — Eldivenler elleri korumak için tasarlanmıştır...
CE XXXX — Ürün, Avrupa Birliği'nin gerektirdiği...
EN ISO 374-2:2016 / A / B / C / D E — Risk değerlendirme...

EN ISO 374-2:2016 / Type A, B, C / K / L / O P S / M — Ocena pred kemijskimi nevarnostmi...

アンセル使い捨て手袋 - カテゴリー III JA

A. 用途 — 本手袋は、主に化学物質の飛散のリスクから手を守ることを目的としており...
CE XXXX — 認定標準に適合する適合性評価...
EN ISO 374-2:2016 / A / B / C / D E — リスク評価...

EN ISO 374-2:2016 / Type A, B, C / K / L / O P S / M — Ocena pred kemijskimi nevarnostmi...

SARUNG TANGAN SEKALI GUNAN ANSELL - KATEGORI III MS

A. Penggunaan — Sarung tangan sekali guna...
CE XXXX — Peranti Perlindungan Diri (PPE) ini...
EN ISO 374-2:2016 / A / B / C / D E — Penilaian risiko...

EN ISO 374-2:2016 / Type A, B, C / K / L / O P S / M — Ocena pred kemijskimi nevarnostmi...

安尔森单用途手套 CAT. III ZH

A. 用途 — 手套的功能是保护双手...
CE XXXX — 产品符合欧盟法规...
EN ISO 374-2:2016 / A / B / C / D E — 风险评估...

EN ISO 374-2:2016 / Type A, B, C / K / L / O P S / M — Ocena pred kemijskimi nevarnostmi...

გუნდენიქეიქეიქეიქეიქეიქეი ANSELL — CAT. III TH

A. การใช้ — ถุงมือชนิดใช้ทิ้ง...
CE XXXX — ผลิตภัณฑ์ได้รับการรับรอง...
EN ISO 374-2:2016 / A / B / C / D E — การประเมินความเสี่ยง...

EN ISO 374-2:2016 / Type A, B, C / K / L / O P S / M — Ocena pred kemijskimi nevarnostmi...

# DICHIARAZIONE DI CONFORMITÀ UE

Il Fabbricante  
ANSELL HEALTHCARE EUROPE N.V.  
RIVERSIDE BUSINESS PARK, BLOCK J  
BOULEVARD INTERNATIONAL 55  
B-1070 BRUSSELS  
BELGIUM

dichiara sotto la propria e unica responsabilità che il DPI descritto di seguito:

**TouchNTuff® 92-500**

*Prodotti fabbricati a partire da: [21/04/2018]*

**DPI da utilizzare contro i rischi di categoria III**

EN ISO 374-1:2016  
Type B



EN ISO 374-5:2016



**J K P T**

è conforme alle disposizioni del regolamento (UE) 2016/425 e alle norme europee armonizzate EN ISO 374-1:2016, EN 420:2003 + A1:2009, EN ISO 374-5:2016, ed è identico al DPI che è soggetto all'esame UE del tipo (modulo B, allegato V al regolamento); con certificato numero 032/2018/0329 rilasciato dall'organismo notificato:

**CENTEXBEL (0493)  
TECHNOLOGIEPARK 70  
B-9052 ZWIJNAARDE  
BELGIUM**

ed è soggetto alla procedura di cui all'allegato VII (modulo C2) del regolamento, sotto la supervisione dell'organismo notificato:

**CENTEXBEL (0493)  
TECHNOLOGIEPARK 70  
B-9052 ZWIJNAARDE  
BELGIUM**

A handwritten signature in black ink, appearing to read "Guido Van Duren".

Guido Van Duren  
Director - Regulatory affairs  
Ansell

Luogo: Bruxelles  
Data: 21/02/2018

# DICHIARAZIONE DI CONFORMITÀ UE

Il Fabbricante  
**ANSELL HEALTHCARE EUROPE N.V.**  
**RIVERSIDE BUSINESS PARK, BLOCK J**  
**BOULEVARD INTERNATIONAL 55**  
**B-1070 BRUSSELS**  
**BELGIUM**

dichiara sotto la propria e unica responsabilità che il DPI descritto di seguito:

**TouchNTuff® 92-500**

*Prodotti fabbricati fino a: [20/04/2018]*

**DPI da utilizzare contro i rischi di categoria III**

**EN 374**



**EN 374**



è conforme alle disposizioni del regolamento (UE) 2016/425 e alle norme europee armonizzate EN 420:2003 + A1:2009, EN 374:2003, ed è identico al DPI che è soggetto all'esame CE del tipo; con certificato numero 032/2016/1184 rilasciato dall'organismo notificato:

**CENTEXBEL (0493)**  
**TECHNOLOGIEPARK 70**  
**B-9052 ZWIJNAARDE**  
**BELGIUM**

ed è soggetto alla procedura di cui all'allegato VII (modulo C2) del regolamento, sotto la supervisione dell'organismo notificato:

**CENTEXBEL (0493)**  
**TECHNOLOGIEPARK 70**  
**B-9052 ZWIJNAARDE**  
**BELGIUM**

Guido Van Duren  
Director - Regulatory affairs  
Ansell

Luogo: Bruxelles  
Data: 25/11/2016

# DICHIARAZIONE DI CONFORMITÀ DEL PRODOTTO PER CONTATTO CON GLI ALIMENTI

L'operatore economico, stabilito nella Comunità europea:

**ANSELL HEALTHCARE EUROPE N.V.  
RIVERSIDE BUSINESS PARK, BLOCK J  
BOULEVARD INTERNATIONAL 55  
B - 1070 BRUSSELS**

dichiara che il guanto descritto di seguito:

**TouchNTuff® 92-500**

appartenente alla categoria "Elastomeri e gomma"

è conforme alle seguenti disposizioni:

regolamento CE 1935/2004 e regolamento CE 2023/2006 in materia di buone pratiche di fabbricazione (GMP) dei materiali e degli oggetti destinati a venire a contatto con prodotti alimentari (per maggiori informazioni, consultare la Dichiarazione di conformità alimentare BPF di Ansell)

Tutti gli ingredienti, monomeri di partenza, additivi nella produzione del guanto sono conformi:

- a qualsiasi elenco positivo;
- a eventuali restrizioni o limiti specifici di migrazione (SML - Specific Migration Limit) pertinenti; secondo quanto specificato nelle normative UE applicabili in materia di prodotti alimentari.

**Francia:** Arrêté du 9 novembre 1994, relatif aux matériaux et objets en caoutchouc au contact des denrées, produits et boissons alimentaires

**Italia:** D.M. 21/03/1973 Disciplina igienica degli imballaggi, recipienti, utensili, destinati a venire in contatto con le sostanze alimentari o con sostanze d'uso personale

**Germania:** BfR Empfehlung XXI (2011) Bedarfsgegenstände auf Basis von Natur- undSynthesekautschuk

**Paesi Bassi:** Regeling Verpakkingen en Gebruiksartikelen (Warenwet), Hoofdstuk III, Rubberproducten Verpakkingen

**Repubblica Ceca:** Vyhláška č. 38/2001 Sb. (Consolidato 2009-5-15) Allegato 07: elastomeri e prodotti in gomma - elenco dei materiali

**Slovacchia:** Výnos MPSR a MZSR z 9. júna 2003 č. 1799/2003 - 100, Annex 10

**FDA Code of Federal Regulations,** Titolo 21, Parte 177, sezione 2600 (21 CFR 177.2600) - Articoli in gomma destinati all'uso ripetuto

## **Ansell Healthcare Europe N.V.**

Riverside Business Park, Block J

Boulevard International 55, 1070 Brussels, Belgium

Tel. +32 (0) 2 528 74 00 • Fax +32 (0) 2 528 74 01

<http://www.ansell.eu> • E-mail [info.europe@ansell.com](mailto:info.europe@ansell.com)



## Dati globali di migrazione:

Tipo di sostanze alimentari - Condizioni di test	Alimenti acquosi  <i>Simulante utilizzato: Acqua distillata</i>	Alimenti alcolici  <i>Simulante utilizzato: Etanolo 10%</i>	Alimenti acidi  <i>Simulante utilizzato: Acido acetico 3%</i>	Fattore di correzione alimenti grassi 1  <i>Simulante utilizzato: Olio di oliva</i>	Fattore di correzione alimenti grassi 2  <i>Simulante utilizzato: Olio di oliva</i>	Fattore di correzione alimenti grassi 3  <i>Simulante utilizzato: Olio di oliva</i>	Fattore di correzione alimenti grassi 4  <i>Simulante utilizzato: Olio di oliva</i>	Fattore di correzione alimenti grassi 5  <i>Simulante utilizzato: Olio di oliva</i>
2 ore/temp. 40°C	< 8 mg/dm <sup>2</sup>	< 8 mg/dm <sup>2</sup>	> 8 mg/dm <sup>2</sup>	< 8 mg/dm <sup>2</sup>	< 8 mg/dm <sup>2</sup>	< 8 mg/dm <sup>2</sup>	< 8 mg/dm <sup>2</sup>	< 8 mg/dm <sup>2</sup>
10 min/40°C	< 10 mg/dm <sup>2</sup>	< 10 mg/dm <sup>2</sup>	< 50 mg/dm <sup>2</sup>					

La tolleranza analitica dei simulanti di alimenti acquosi, alcolici e acidi è di 1 mg/dm<sup>2</sup>, mentre per i simulanti di alimenti grassi è 3 mg/dm<sup>2</sup>, in base alla norma EN1186.

**Istruzioni per la conservazione:** non esporre alla luce diretta del sole; conservare in un locale fresco ed asciutto, all'interno dell'imballaggio originale. Tenere lontano da fonti di ozono. Se conservati correttamente, come indicato in precedenza, i guanti non perdono le loro prestazioni, né subiscono variazioni rilevanti delle loro caratteristiche. Se i guanti possono risentire dell'invecchiamento o del periodo di conservazione, la data di scadenza viene riportata sui materiali di imballaggio.



Guido Van Duren  
Director - Regulatory affairs  
Ansell

Data 26/10/2020

**Ansell Healthcare Europe N.V.**  
Riverside Business Park, Block J  
Boulevard International 55, 1070 Brussels, Belgium  
Tel. +32 (0) 2 528 74 00 • Fax +32 (0) 2 528 74 01  
<http://www.ansell.eu> • E-mail [info.europe@ansell.com](mailto:info.europe@ansell.com)



# EU DECLARATION OF CONFORMITY

The Manufacturer  
**ANSELL HEALTHCARE EUROPE N.V.**  
**RIVERSIDE BUSINESS PARK, BLOCK J**  
**BOULEVARD INTERNATIONAL 55**  
**B-1070 BRUSSELS**  
**BELGIUM**

declares under his sole responsibility, that the PPE described hereafter:

**TouchNTuff® 92-500**

*Products manufactured as of: [21/04/2018]*

**PPE to be used against category III risks**

EN ISO 374-1:2016  
Type B



EN ISO 374-5:2016



VIRUS

**J K P T**

is in conformity with the provisions of Regulation (EU) 2016/425 and with the European harmonized standards EN ISO 374-1:2016, EN 420:2003 + A1:2009, EN ISO 374-5:2016 and is identical to the PPE which is subject to the EU-Type examination (Module B, Annex V of the Regulation), under certificate number 032/2018/0329, issued by the Notified Body:

**CENTEXBEL (0493)**  
**TECHNOLOGIEPARK 70**  
**B-9052 ZWIJNAARDE**  
**BELGIUM**

and is subject to the procedure set out in Annex VII (Module C2) of the Regulation under the supervision of the Notified Body:

**CENTEXBEL (0493)**  
**TECHNOLOGIEPARK 70**  
**B-9052 ZWIJNAARDE**  
**BELGIUM**

A handwritten signature in black ink, appearing to read 'Guido Van Duren'.

**Guido Van Duren**  
**Director - Regulatory affairs**  
**Ansell**

**Place: Brussels**  
**Date: 21/02/2018**

# EU DECLARATION OF CONFORMITY

The Manufacturer  
**ANSELL HEALTHCARE EUROPE N.V.**  
**RIVERSIDE BUSINESS PARK, BLOCK J**  
**BOULEVARD INTERNATIONAL 55**  
**B-1070 BRUSSELS**  
**BELGIUM**

declares under his sole responsibility, that the PPE described hereafter:

**TouchNTuff® 92-500**

*Products manufactured till: [20/04/2018]*

**PPE to be used against category III risks**

EN 374



EN 374



is in conformity with the provisions of Regulation (EU) 2016/425 and with the European harmonized standards EN 420:2003 + A1:2009, EN 374:2003, and is identical to the PPE which is subject to the EC Type examination; under certificate number 032/2016/1184 issued by the Notified Body:

**CENTEXBEL (0493)**  
**TECHNOLOGIEPARK 70**  
**B-9052 ZWIJNAARDE**  
**BELGIUM**

and is subject to the procedure set out in Annex VII (Module C2) of the Regulation under the supervision of the Notified Body:

**CENTEXBEL (0493)**  
**TECHNOLOGIEPARK 70**  
**B-9052 ZWIJNAARDE**  
**BELGIUM**



Guido Van Duren  
Director - Regulatory affairs  
Ansell

Place: Brussels  
Date: 25/11/2016



# FOOD DECLARATION OF PRODUCT COMPLIANCE

The Business Operator, established in the European Community:

**ANSELL HEALTHCARE EUROPE N.V.  
RIVERSIDE BUSINESS PARK, BLOCK J  
BOULEVARD INTERNATIONAL 55  
B-1070 BRUSSELS**

declares that the glove described hereafter:

**TouchNTuff® 92-500**

belonging to the "Elastomers & Rubber" category

is in conformity with the following provisions:

the EC-regulation 1935/2004 and the EC-regulation 2023/2006 related to Good Manufacturing Practices (GMP) for Materials and Articles intended to come in contact with Foodstuffs (for more detailed information please also consult Ansell GMP Food Declaration).

All ingredients, starting monomers, additives used in manufacturing this glove comply with:

- any positive list
- any relevant SML(Specific Migration Limit) or restrictions as specified in the applicable EU food legislations.

**France:** Arrêté du 9 novembre 1994, relatif aux matériaux et objets en caoutchouc au contact des denrées, produits et boissons alimentaires

**Italy:** D.M. 21/03/1973 Disciplina igienica degli imballaggi, recipienti, utensili, destinati a venire in contatto con le sostanze alimentari o con sostanze d'uso personale

**Germany:** BfR Empfehlung XXI (2011) Bedarfsgegenstände auf Basis von Natur- und Synthesekautschuk

**Netherlands:** Regeling Verpakkingen en Gebruiksartikelen (Warenwet), Hoofdstuk III, Rubberproducten Verpakkingen

**Czech Republic:** Vyhláška č. 38/2001 Sb. (Consolidated 2009-5-15) Annex 07: Elastomers and rubber products - list of materials

**Slovakia:** Výnos MPSR a MZSR z 9. júna 2003 č. 1799/2003 - 100, Annex 10

**FDA Code of Federal Regulations,** Title 21, Part 177, section 2600 (21 CFR 177.2600) - Rubber articles intended for repeated use

**Ansell Healthcare Europe N.V.**

Riverside Business Park, Block J

Boulevard International 55, 1070 Brussels, Belgium

Tel. +32 (0) 2 528 74 00 • Fax +32 (0) 2 528 74 01

<http://www.ansell.eu> • E-mail [info.europe@ansell.com](mailto:info.europe@ansell.com)



## Global migration data:

Type of foodstuffs - Testing conditions	Aqueous food	Alcoholic food	Acidic food	Fatty food correction factor 1	Fatty food correction factor 2	Fatty food correction factor 3	Fatty food correction factor 4	Fatty food correction factor 5
	<i>Simulant used: Distilled Water</i>	<i>Simulant used: Ethanol 10%</i>	<i>Simulant used: Acetic acid 3%</i>	<i>Simulant used: Olive oil</i>	<i>Simulant used: Olive oil</i>	<i>Simulant used: Olive oil</i>	<i>Simulant used: Olive oil</i>	<i>Simulant used: Olive oil</i>
2 hours/temp. 40°C	< 8 mg/dm <sup>2</sup>	< 8 mg/dm <sup>2</sup>	> 8 mg/dm <sup>2</sup>	< 8 mg/dm <sup>2</sup>	< 8 mg/dm <sup>2</sup>	< 8 mg/dm <sup>2</sup>	< 8 mg/dm <sup>2</sup>	< 8 mg/dm <sup>2</sup>
10min/40°C	< 10 mg/dm <sup>2</sup>	< 10 mg/dm <sup>2</sup>	< 50 mg/dm <sup>2</sup>					

Analytical tolerance for aqueous, alcoholic and acidic food simulant is 1mg/dm<sup>2</sup> and for fatty food simulant is 3mg/dm<sup>2</sup> as per EN 1186.

**Storage instruction:** Keep away from direct sunlight; store in a cool dry place and keep in the original packaging. Keep away from ozone sources. If gloves are properly stored, as indicated above, they won't lose their performances and won't change the glove characteristics significantly. If gloves could be affected by ageing or storage, the expiry date is mentioned on the packaging materials.



Guido Van Duren  
Director - Regulatory affairs  
Ansell

Date 27/10/2020

**Ansell Healthcare Europe N.V.**  
Riverside Business Park, Block J  
Boulevard International 55, 1070 Brussels, Belgium  
Tel. +32 (0) 2 528 74 00 • Fax +32 (0) 2 528 74 01  
<http://www.ansell.eu> • E-mail [info.europe@ansell.com](mailto:info.europe@ansell.com)

