

EU-overensstemmelseserklæring







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CERTIFICERING AF PERSONLIGE VÆRNEMIDLER - KATEGORI III

Otto Schachner Nordic
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erklærer herved, at nedennævnte personlige værnemiddel

Nilex nitril PF - best. nr. 608 XXX

Kemikalier	Mikroorganismer	Migrationstestet	Pesticider
EN ISO 374-1:2016+A1:2018/Type B	EN ISO 374-5:2016	1935/2004	ISO 18889:2019
			
KPT	VIRUS		G1

er i overensstemmelse med EU harmoniseringslovgivning PPE forordning (EU) 2016/425 om sikkerhedskrav m.v. til personlige værnemidler, der gennemfører de harmoniserede standarder nr. EN ISO 21420:2020 (generelle krav), EN 455-1:2020, (medicinsk standard), ,EN ISO 374-1:2016+A1:2018/Type B (kemikalier), EN ISO 374-4:2019, EN ISO 374-5:2016(mikroorganismer), ISO 18889:2019 (pesticider)

Testet i henhold til regulativ nr. 10/2011/EU og EU-forordning nr. 1935/2004 om kontakt med fødevarer – Se venligst specifikationerne i slutningen af dette dokument.


Nilex nitril PF, best. nr. 608 xxx er identisk med det personlige værnemiddel, for hvilket der er udstedt CE-typeafprøvningsattest 2777/19664-01/E03-02 af den godkendte institution

SATRA Technology Europe Limited
Bracetown Business Park
CloneeD15YN2P
Republic of Ireland
(Reg. Nr. 2777)

Er underlagt proceduren, der er fastlagt i modul D under overvågning af det bemyndigede organ:

SGS Fimko Oy
P.O. Box 30 (Särkiniementie 3)
00211 Helsinki
Finland
(Reg. Nr. 0598)

Udfærdiget i Fredericia, den 31. august 2023


Janette Bundgaard

EU Declaration of Product Conformity







CERTIFICATION OF PERSONAL PROTECTIVE EQUIPMENT – CATEGORY III

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hereby declares that the PPE described hereafter

Nilex nitril PF - art. no. 608 XXX

Chemicals	Micro organisms	Migration tested	Pesticides
EN ISO 374-1:2016+A1:2018/Type B	EN ISO 374-5:2016	1935/2004	ISO 18889:2019
			
KPT	VIRUS		G1

is in conformity with the provisions of the regulation (EU) 2016/425 on personal protective equipment and with the national standard introducing the European standards: EN ISO 21420:2020 (General requirements), EN 455-1:2020 (Medical), EN ISO 374-1:2016+A1:2018/Type B (Chemicals), EN ISO 374-4:2019, EN ISO 374-5:2016 (Micro-organisms), ISO 18889:2019 (Pesticides).

In accordance with the regulation no. 10/2011/EU and EU regulation no. 1935/2004 on Contact with foodstuff – Please check the specifications at the end of this document.

Nilex nitril PF, art. no. 608 xxx is identical with the personal protective equipment for which CE Type-examination certificate no. 2777/19664-01/E03-02 issued by the notified body

SATRA Technology Europe Limited
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and is subject to the procedure outlined in Module D under the supervision of the notified body:

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(Notified body. 0598)

Issued Fredericia, 31. August 2023


Janette Bundgaard

EU-Konformitätserklärung



ZERTIFIZIERUNG VON PERSÖNLICHE SCHUTZAUSRÜSTUNG – KATEGORIE III otto schachner nordic
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erklären hierdurch, dass die untengenannte persönliche Schutzausrüstung

Nilex nitril PF - Best. Nr. 608 XXX

Chemikalien
EN ISO 374-1:2016+A1:2018/Type B



KPT

Mikroorganismen
EN ISO 374-5:2016



VIRUS

Migrationsgetestet
1935/2004



Pestizide
ISO 18889:2019



G1

in Übereinstimmung mit der EU Harmonisierungsrechtsvorschriften der PSA Verordnung (EU) 2016/425 über Sicherheitsanforderungen an persönlichen Schutzausrüstungen ist, die die harmonisierten Standards:

EN ISO 21420:2020 (allgemeine Anforderungen), EN 455-1:2020 (Medical), EN ISO 374-1:2016+A1:2018/Type B (Chemikalien), EN ISO 374-4:2019, EN ISO 374-5:2016 (Mikroorganismen), ISO 18889:2019 (Pestizide).

Gemäß der Verordnung Nr. 10/2011/EU und EUVerordnung Nr. 1935/2004 über den Kontakt mit Lebensmitteln – Bitte beachten Sie die Spezifikationen am Ende dieses Dokuments

Nilex nitril PF, Best. Nr. 608 xxx ist mit der PSA identisch, für die die EU-Baumusterprüfbescheinigung 2777/19664-01/E03-02 ausgefertigt ist von der notifizierte Stelle:

SATRA Technology Europe Limited
Bracetown Business Park
Clonee D15YN2P
Republic of Ireland
(Reg. Nr. 2777)

Und dem in Modul D der Verordnung beschriebenen Verfahren unter Aufsicht der benannten Stelle unterliegt:

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(Reg. Nr. 0598)

Ausgefertigt Fredericia, 31. August 2023


Janette Bundgaard



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Testdata re. Contact with Foodstuff: Regulation No. 10/2011/EU, EU Regulation No. 1935/2004 etc.:

Tests required	Evaluation
Heavy metals, specific migration	Pass
Lead and Cadmium, total content	Pass
Overall migration - simulant B - 3% Acetic acid	Pass
Overall migration - simulant 95% Ethanol	Pass
Overall migration - simulant Isooctane	Pass
PAH (Polycyclic aromatic hydrocarbons)	Pass
Phthalates, specific migration	Pass
Phthalates	Pass
Sensory test - change of odour and taste through direct contact, fatty food (aqueous) - coconut oil	Pass
Sensory test - change of odour and taste through direct contact, acidic and aqueous food - still water	Pass

Test Method / Standard: Overall migration - simulant B - 3% Acetic acid: EN 1186			
Test Location: Parameter has been analyzed at BVCPS laboratory Schwerin.			
Parameter	Limit	Result	Evaluation
Test duration		10 Minuten	No Specification
Analysis of		1. Migrate	No Specification
Temperature		40°C	No Specification
Test result	≤ 10 mg/dm ²	<2.5 mg/dm ²	Pass
Volume		40 ml	No Specification
Surface area		0.43 dm ²	No Specification
Test Method / Standard: Overall migration - simulant 95% Ethanol: EN 1186			
Test Location: Parameter has been analyzed at BVCPS laboratory Schwerin.			
Parameter	Limit	Result	Evaluation
Test duration		10 Minuten	No Specification
Analysis of		1. Migrate	No Specification
Temperature		40°C	No Specification
Test result	≤ 10 mg/dm ²	5.20 mg/dm ²	Pass
Volume		40 ml	No Specification
Surface area		0.43 dm ²	No Specification
Test Method / Standard: Overall migration - simulant Isooctane: EN 1186			
Test Location: Parameter has been analyzed at BVCPS laboratory Schwerin.			
Parameter	Limit	Result	Evaluation
Test duration		5 minutes	No Specification
Analysis of		1. Migrate	No Specification
Temperature		20°C	No Specification
Test result	≤ 10 mg/dm ²	<2.5 mg/dm ²	Pass
Volume		40 ml	No Specification
Surface area		0.43 dm ²	No Specification



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Test Method / Standard:	Phthalates: DIN EN ISO 14389 (modified), extraction with THF/ACN followed by GC-MS and/or LC-MS analysis, reporting limit: 50 mg/kg		
Test Location:	Parameter has been analyzed at BVCPS laboratory Schwerin.		
Parameter	Limit	Result	Evaluation
Dibutylphthalate (DBP)	≤ 0.05 %	<0.005 %	Pass
Benzylbutylphthalate (BBP)	≤ 0.1 %	<0.005 %	Pass
Di(2-ethylhexyl)phthalate (DEHP)	≤ 0.1 %	<0.005 %	Pass
Di-iso-nonylphthalate (DINP)	≤ 0.1 %	<0.005 %	Pass
Di-iso-decylphthalate (DIDP)	≤ 0.1 %	<0.005 %	Pass

Test Method / Standard:	Lead & Cadmium, total content: DIN EN 14602, total metal content, microwave digestion with salpetric acid/ hydrochloric acid, determination using ICP, reporting limit : 1 mg/kg		
Test Location:	Parameter has been analyzed at BVCPS laboratory Schwerin.		
Parameter	Limit	Result	Evaluation
Cadmium (Cd)	≤ 100 mg/kg	<1 mg/kg	Pass
Lead (Pb)	≤ 100 mg/kg	<1 mg/kg	Pass

Test Method / Standard:	Sensory test - change of odour and taste through direct contact, fatty food (aqueous) - coconut oil: DIN 10955		
Test Location:	Parameter has been analyzed at BVCPS laboratory Schwerin.		
Parameter	Limit	Result	Evaluation
Change of odour (grade)	≤ 2.5	0	Pass
Change of taste (Grade)	≤ 2.5	0	Pass
Test duration		10 Minuten	No Specification
Temperature		40°C	No Specification

Test Method / Standard:	Sensory test - change of odour and taste through direct contact, acidic and aqueous food - still water: DIN 10955		
Test Location:	Parameter has been analyzed at BVCPS laboratory Schwerin.		
Parameter	Limit	Result	Evaluation
Change of odour (grade)	≤ 2.5	0	Pass
Change of taste (Grade)	≤ 2.5	0	Pass
Test duration		10 Minuten	No Specification
Temperature		40°C	No Specification