

EU-overensstemmelseserklæring (DK)



otto schachner nordic
MEMBER OF CIERVA GROUP

CERTIFICERING AF PERSONLIGE VÆRNEMIDLER - KATEGORI III

**Otto Schachner Nordic
Prinsessens Kvarter 2
DK-7000 Fredericia**

erklærer herved, at nedennævnte personlige værnemiddel

Nilex Black PF - best. nr. 606 XXX

Kemikalier
**EN ISO 374-
1:2016/Type B**



KPT

Mikroorganismer
**EN ISO 374-
5:2016**



VIRUS

Migrationstestet
EN 1186-1:2002



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 ISO 374-1:2016/Type B (kemikalier), EN ISO 374-4:2019, EN ISO 374-5:2016 (mikroorganismer).

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 Black PF, best. nr. 606 xxx er identisk med det personlige værnemiddel, for hvilket der er udstedt CE-typeafprøvningsattest 2777/17447-03/E24-01 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/C2 under overvågning af det bemyndigede organ:

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

Udfærdiget i Fredericia, den 06. maj 2024


Janette Bundgaard

EU Declaration of Product Conformity (EN)



CERTIFICATION OF PERSONAL PROTECTIVE EQUIPMENT – CATEGORY III

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MEMBER OF CIERVA GROUP

Otto Schachner Nordic
Prinsessens Kvarter 2
DK-7000 Fredericia

hereby declares that the PPE described hereafter

Nilex Black PF - art. no. 606 XXX

Chemicals
EN ISO 374-1:2016/Type B



KPT

Micro organisms
EN ISO 374-5:2016



VIRUS

Migration tested
EN 1186-1:2002



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 ISO 374-1:2016/Type B (Chemicals), EN ISO 374-4:2019, EN ISO 374-5:2016 (Micro-organisms).

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 Black PF, art. no. 606 xxx is identical with the personal protective equipment for which CE Type-examination certificate no. 2777/17447-03/E24-01 issued by the notified body

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and is subject to the procedure outlined in Module D/C2 under the supervision of the notified body:

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Bracetown Business Park
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Republic of Ireland
(Notified body. 2777)

Issued Fredericia, 06. May 2024


Janette Bundgaard

EU-Konformitätserklärung (DE)



ZERTIFIZIERUNG VON PERSÖNLICHE SCHUTZAUSRÜSTUNG – KATEGORIE III otto schachner nordic
MEMBER OF CIERVA GROUP

Otto Schachner Nordic
Prinsessens Kvarter 2
DK-7000 Fredericia

erklären hierdurch, dass die untengenannte persönliche Schutzausrüstung

Nilex Black PF - Best. Nr. 606 XXX

Chemikalien
EN ISO 374-1:2016/Type B



KPT

Mikroorganismen
EN ISO 374-5:2016



VIRUS

Migrationsgetestet
EN 1186-1:2002



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 ISO 374-1:2016/Type B, (Chemikalien), EN ISO 374-4:2019, EN ISO 374-5:2016 (Mikroorganismen).

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 Black PF, Best. Nr. 606 xxx ist mit der PSA identisch, für die die EU-Baumusterprüfbescheinigung 2777/17447-03/E24-01 ausgefertigt ist von der notifizierte Stelle:

SATRA Technology Europe Limited
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Und dem in Modul D/C2 der Verordnung beschriebenen Verfahren unter Aufsicht der benannten Stelle unterliegt:

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

Ausgefertigt Fredericia, 06. Mai 2024


Janette Bundgaard

EU-överensstämmelseförklaring (SE)



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MEMBER OF CIERVA GROUP

CERTIFIERING AV PERSONLIG SKYDDSUTRUSTNING – KATEGORI III

Otto Schachner Nordic
Prinsessens Kvarter 2
DK-7000 Fredericia

förklarar härmed att följande personliga skyddsutrustning

Nilex Black PF - art. nr. 606 XXX

Kemikalier
EN ISO 374-1:2016/Type B



KPT

Mikroorganismer
EN ISO 374-5:2016



VIRUS

Migrationsprovet
EN 1186-1:2002



är i överensstämmelse med EU:s harmoniserade lagstiftning om personlig skyddsutrustning (PPE) förordning (EU) 2016/425 om säkerhetskrav med mera för personliga skyddsutrustningar, som genomförde harmoniserade standarderna nr.:

EN ISO 21420:2020 (allmänna krav), EN ISO 374-1:2016/Type B (kemikalier), EN ISO 374-4:2019, EN ISO 374-5:2016 (mikroorganismer).

Enligt förordning nr 10/2011/EU och EU-förordning nr 1935/2004 om kontakt med livsmedel - Vänligen kontrollera specifikationerna längst ner i detta dokument.

Nilex Black PF, art. nr. 606 xxx är identisk med personlig skyddsutrustning för vilken CE-typundersökningsintyg nr. 2777/17447-03/E24-01 utfärdad av den anmälda organet:

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och är föremål för förfarandet som beskrivs i Modul D/C2 under övervakning av den notifierade organet:

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Republic of Ireland
(Notified body. 2777)

Utfärdat i Fredericia, 06. maj 2024


Janette Bundgaard

EU:n vaatimustenmukaisuusvakuutus (FI)



SERTIFIOINTI HENKILÖKOHTAISILLE SUOJAVÄLINEILLE - KATEGORIA III

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täten vakuuttaa, että jäljempänä kuvattu henkilönsuojain

Nilex Black PF - tuotenumeron 606 XXX

Kemialliset
**EN ISO 374-
1:2016/Type B**



KPT

Mikro-organismit
**EN ISO 374-
5:2016**



VIRUS

Migraatiotesti
EN 1186-1:2002



on EU:n henkilökohtaisten suojavarusteiden turvallisuusvaatimusten mukainen asetuksen (EU) 2016/425 kanssa sekä kansallisen standardin, joka ottaa käyttöön eurooppalaisen standardin:

EN ISO 21420:2020 (yleiset vaatimukset), EN ISO 374-1:2016/Type B (kemikaaleja), EN ISO 374-4:2019, EN ISO 374-5:2016 (mikro-organismit).

Vastaavasti asetuksen nro. 10/2011/EU ja EU-asetuksen nro. 1935/2004 mukaisesti koskien elintarvikkeisiin kosketusta - Ole hyvä ja tarkista tämän asiakirjan lopussa olevat tekniset tiedot. Nilex Black PF, tuotenumeron 606 xxx on identtinen henkilökohtaisen suojavarusteen kanssa, jonka CE-tyyppitutkimustodistus nro [rapport nr] on myöntänyt ilmoitettu laitos:

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(Notified body. 2777)

ja on alainen menettelylle, joka on esitetty Moduulissa D/C2 valvovan ilmoitetun laitoksen valvonnassa:

SATRA Technology Europe Limited
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Republic of Ireland
(Notified body. 2777)

on annettu Fredericiassa, 06. toukokuu 2024


Janette Bundgaard

EU-conformiteitsverklaring (NL)




CERTIFICERING VAN PERSOONLIJKE BESCHERMINGSMIDDELEN
CATEGORIE III



**Otto Schachner Nordic
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verklaart hierbij dat de hierna omschreven PBM

Nilex Black PF - item nr. 606 XXX

| Chemische stoffen | Micro-organismen | Migratietest |
|---|---|--|
| EN ISO 374-1:2016/Type B | EN ISO 374-5:2016 | EN 1186-1:2002 |
|  |  |  |
| KPT | VIRUS | |

in overeenstemming zijn met de bepalingen van de regelgeving (EU) 2016/425 van het Europese Parlement en van de raad betreffende persoonlijke beschermingsmiddelen overeenkomstig de geharmoniseerde norm(en):

EN ISO 21420:2020 (algemene eisen), EN ISO 374-1:2016/Type B (chemische stoffen), EN ISO 374-4:2019, EN ISO 374-5:2016 (micro-organismen).

In overeenstemming met verordening nr. 10/2011/EU en EU-verordening nr. 1935/2004 betreffende contact met levensmiddelen - Gelieve de specificaties aan het einde van dit document te controleren. Nilex Black PF, item nr. 606 xxx is identiek aan de persoonlijke beschermingsmiddelen door CE-inspectiecertificaat 2777/17447-03/E24-01 afgegeven door de aangemelde instantie:

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De PBM zijn onderworpen aan interne productiecontrole plus productcontroles onder toezicht op willekeurige intervallen (Module D/C2) onder toezicht van de aangemelde instantie.

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Afgegeven in Fredericia, 06. mei 2024


Janette Bundgaard

Déclaration de conformité UE (FR)



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CERTIFICATION DES ÉQUIPEMENTS DE PROTECTION INDIVIDUELLE
CATÉGORIE III

**Otto Schachner Nordic
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DK-7000 Fredericia**

déclare par la présente que l'EPI décrit ci-après

Nilex Black PF - article n° 606 XXX

Chimiques
**EN ISO 374-
1:2016/Type B**



KPT

micro-organismes
**EN ISO 374-
5:2016**



VIRUS

Migration testé
EN 1186-1:2002



est conforme aux dispositions du règlement (UE) 2016/425 du Parlement européen et du conseil relatif aux équipements de protection individuelle selon la ou les normes harmonisées :
EN ISO 21420:2020 (généralités), EN ISO 374-1:2016/Type B (micro-organismes), EN ISO 374-4:2019, EN ISO 374-5:2016 (Micro-organisms).

Conformément au règlement n° 10/2011/UE et au règlement UE n° 1935/2004 relatif aux contacts avec les denrées alimentaires - Veuillez vérifier les spécifications à la fin de ce document.

Nilex Black PF, art. no. 606 xxx is identical with the personal protective equipment for which CE Type-examination certificate no. 2777/17447-03/E24-01 issued by the notified body

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Issued Fredericia, 06. mai 2024


Janette Bundgaard

The gloves are in conformity with EU Regulation 1935/2004:



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Test Requested and Conclusion(s):

| No. | Test Sample | Standard and Requirement | Conclusion(s) |
|-----|------------------|---|---------------|
| 1) | Submitted sample | According to Regulation EU 1935/2004/EC & EU 10/2011& (EU) 2020/1245. - Sensory test - Overall Migration - Specific migration of Primary Aromatic Amine (PAA) - Specific Migration of Heavy metals - Specific migration of Nitrosamine and nitrosatable substances | PASS |
| 2) | Submitted sample | German Food, Articles of Daily Use and Feed Code of September 1, 2005 (LFGB), Section 30 & 31 with amendments and BfR recommendation III and BfR Recommendation L&VI. & European Commission Regulation (EU) No 10/2011 with amendments. - Total butadiene | PASS |

Test Result(s):

1) According to Regulation EU 1935/2004/EC & EU 10/2011& (EU) 2020/1245.

1.1) Sensory test

Method: With reference to DIN 10955:2004.

No.of panelist: 6.

| Test Item(s). | Test condition | Limit | Result | Conclusion |
|--|------------------------------|-------|--------|------------|
| | | | 1 | |
| Sensorial examination odour (Point scale). | 23°C, 24h | 2.5 | 1 | PASS |
| Sensorial examination taste (Point scale). | 23°C, 24h Distilled water | 2.5 | 0 | PASS |

Notes: Scale evaluation:

0= no aberration, neutral

1= very slight deterioration, barely perceivable

2= slight deterioration

3= significant deterioration

4= strong deterioration

1.2) Overall migration

Method: EN 1186-1:2002 & EN 1186-3:2002 & EN 1186-2:2002

Test condition: 40°C for 0.5h in 10% Ethanol / 3% Acetic acid / Olive oil.

| Simulant Used(s) | Unit | Limit(s) | RL | Result(s) | Conclusion(s) |
|------------------|--------------------|----------|----|-----------|---------------|
| | | | | 1 | |
| 10% Ethanol | mg/dm ² | 10 | 3 | N.D. | PASS |
| 3% Acetic acid | mg/dm ² | 10 | 3 | 3.8 | PASS |
| Olive oil | mg/dm ² | 10 | 3 | N.D. | PASS |

Note: 1. mg/dm² = milligram per square decimeter.

2. N.D. = Not Detected (< RL).

3. RL = Reporting Limit.

4. Solvents & test condition were selected based on Client's request.

Testdata re. Contact with Foodstuff: Regulation No. 10/2011/EU, EN1186, etc.:



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The tested items **complied with** the requirements of German Food & Feed Acts of September 1, 2005 (LFGB), Section 30 and 31.

- Overall migration test **001 PASS**
 - Extractable formaldehyde **001 PASS**
 - Total lead and zinc content **001 PASS**
 - Color release **001 PASS**
 - Sensory test **002 PASS**
- As per client's request
- Total Cadmium content **001 PASS**

1. Overall Migration Test

- Test method: In accordance with REGULATION (EU) No 10/2011 and its amendments on plastic materials and articles intended to come into contact with food.
- As specified in REGULATION (EU) No 10/2011 and its amendments; with reference to EN 1186: Part 4 (Test methods for overall migration into olive oil by cell)/ EN 1186: Part 5 (Test methods for overall migration into aqueous food simulants by cell)
- Migration ratio (S/V): 10dm²/L

| Simulant(s) Used | Test Condition | Result(s) [mg/dm ²] | Maximum Permissible Limit [mg/dm ²] |
|------------------|-------------------|---------------------------------|---|
| | | 001 | |
| 3% Acetic acid | 40°C for 0.5 hour | 4.80 | 10 |
| 10% Ethanol | 40°C for 2 hours | 4.20 | 10 |
| Olive Oil | 40°C for 2 hours | <0.500 | 10 |

2. Extractable formaldehyde

- Test method: For compliance with the Recommendation of the BfR "Kunststoffe im Lebensmittelverkehr" Part XXI. Commodities based on Natural and Synthetic Rubber
- With reference to Section 2.7.1 of methods for the "Testing of commodities made of rubber"
- Test condition: 3% Acetic acid, 40°C for 0.5 hour
- Migration ratio (S/V): 6dm²/L

| Test Item(s) | Result(s) [µg/ml] | Maximum Permissible Limit [µg/ml] |
|--------------------------|-------------------|-----------------------------------|
| | 001 | |
| Extractable Formaldehyde | <0.10 | 3 |

3. Total lead and zinc content

- Test method: Acid digestion, then followed by ICP-OES

| Test Item(s) | Result(s) [%] | Maximum Permissible Limit [%] |
|--------------|---------------|-------------------------------|
| | 001 | |
| Lead content | <0.001 | 0.003 |
| Zinc content | 0.525 | 3.0 |

4. Color release

- Test method: With reference to Kunststoffe im Lebensmittelverkehr Book II, Teil B II, IX

| Simulant(s) Used | Test Condition | Result(s) | Permissible Limit |
|------------------|------------------|-------------|-------------------|
| | | 001 | |
| 10% Ethanol | 50°C for 5 hours | No bleeding | No bleeding |
| 2% Acetic acid | 50°C for 5 hours | No bleeding | No bleeding |
| Peanut oil | 50°C for 5 hours | No bleeding | No bleeding |
| Water | 50°C for 5 hours | No bleeding | No bleeding |



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5. Sensory test

- Test method: With reference to DIN 10955.
- The submitted sample was immersed in distilled water at 40°C for 2 hours. After this treatment treated water was examined by panels with regard to any divergence in smell and taste.

| Sample(s) | Testing Parameter | Grading result(s) | Recommended level |
|-----------|-------------------|-------------------|-------------------|
| 002 | Transfer of taste | 0.5 | <3 |
| | Transfer of smell | 0.5 | <3 |

Note: 1. Available grading are listed as follow:

Grading 0: No perceptible taste/smell deviation

1: Just perceptible taste/smell deviation

2: Weak taste/smell deviation

3: Clear taste/smell deviation

4: Strong taste/smell deviation

6. Total Cadmium content

| Test Item(s) | Result(s) [mg/kg] | Maximum Permissible Limit* [mg/kg] |
|-----------------------|-------------------|---------------------------------------|
| | 001 | |
| Total Cadmium Content | <2 | 2 |