EU-Konformitätserklärung Nr. 151

Persönliche Schutzausrüstung

Nitril Viola, Untersuchungshandschuh aus Nitril, puderfrei, latexfrei, unsteril, Farbe violett, REF1285, Größen: S, M, L, XL

Name und Anschrift des Herstellers

Meditrade GmbH
Medipark 1
83088 Kiefersfelden
Germany

Die alleinige Verantwortung für die Ausstellung dieser Konformitätserklärung trägt der Hersteller.

Gegenstand der Erklärung

Der oben beschriebene Gegenstand der Erklärung entspricht den einschlägigen Harmonisierungsrechtsvorschriften der Union:

- EN ISO 374-1:2016+A1:2018/Typ B
- EN ISO 374-5:2016
- EN ISO 21420:2020
- Verordnung (EU) 2016/425

Die notifizierte Stelle (SATRA, 2777) hat die EU-Baumusterprüfung durchgeführt und die EU-Baumusterprüfbescheinigung (Nr. 2777/14815-03/E15-01, gültig bis 20/07/2025) ausgestellt. Die PSA unterliegt folgendem Konformitätsbewertungsverfahren durch die notifizierte Stelle (SATRA, Nr. 2777): Konformität mit dem Baumuster auf der Grundlage einer Qualitätssicherung bezogen auf den Produktionsprozess (Modul C2) gemäß Anhang VII.

Kiefersfelden, den 17.02.2022

Martin Unterberg
Regulatory Affairs/ Quality Management

CE Declaration of Conformity No. 151

Personal Protective Equipment
Nitril Viola, nitrile examination glove, powder-free, latex-free, non-sterile, colour violet, REF1285, sizes: S, M, L, XL

Name and Address of the Manufacturer

Meditrade GmbH
Medipark 1
83088 Kiefersfelden
Germany

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Object of the Declaration

The object of the declaration described above is in conformity with the relevant Union harmonisation legislation:

- EN ISO 374-1:2016+A1:2018/Type B
- EN ISO 374-5:2016,
- EN ISO 21420:2020
- Regulation (EU) 2016/425

The notified body (SATRA, 2777) carried out the EU type examination and issued the EU type examination certificate (No. 2777/14815-03/E15-01, valid until 20/07/2025). The PPE is subject to the following conformity assessment procedure by the notified body (SATRA, 2777): Conformity to type based on quality assurance of the production process (module C2) according to Annex VII.

Kiefersfelden, 17.02.2022

Martin Unterberg
Regulatory Affairs/ Quality Management

Issued to:

Meditrade GmbH
Medipark 1
83088 Kiefersfelden
Germany

Notified Body: 2777

SATRA customer number: P21130

EU Type-Examination Certificate

Certificate number: 2777/14815-03/E15-01

This EU Type-Examination Certificate covers the following product group(s) supported by testing to the relevant standards/technical specifications and examination of the technical file documentation:
Following the EU Type-Examination this product group has been shown to satisfy the applicable essential health and safety requirements of Annex II of the PPE Regulation (EU) 2016/425 as a Category III product.

Product reference:

Blue:
Nitril® NextGen®, REF 1283(XS-XL)
Nitril® BestGen®, REF 1286(XS-XL)
Nitril® Sensory® Blue, REF 2283(XS-XL)

Black:
Nitril® Black, REF 1284(XS-XL)

White:
Nitril® 3000, REF 1280(XS-XL)
Nitril® Sensory® White, REF 2280(XS-XL)

Violet:
Nitril® Viola, REF 1285(XS-XL)

Description:

Disposable Nitrile Gloves (Non-sterile).

Sizes:
6-10(XS-XL)

Classification:

EN ISO 374-1:2016+A1:2018/Type B	**Level**	**EN ISO 374-4:2019 Degradation %**
40% Sodium hydroxide (K)	6	-68.1
30% Hydrogen peroxide (P)	2	30.5
37% Formaldehyde (T)	5	9.5

EN ISO 374-5:2016	
Protection against Bacteria and Fungi	Pass
Protection against Viruses	Pass

Standards/Technical specifications applied:
EN ISO 21420:2020; EN ISO 374-1:2016+A1:2018; EN ISO 374-5:2016

Technical reports/Approval documents:
SATRA: CHT0296241/2012, CHM0298100/2020/EN/A, CHM0298100/2020/EN/B
SGS: CH:TX:1142011147, CH:TX:1142011145-1, CH:TX:1142011148
TUV: 7191234075-CHM20-02-TSL, 7191235025-EEC20-WBH_CR1, 721652920

Signed on behalf of SATRA:

Geoff Graham

Date of issue: 14/02/2022
Expiry date: 20/07/2025

TERMS AND CONDITIONS

The following conditions apply in addition to SATRA's standard terms and conditions of business and those given in the current certification agreement. This certificate has been issued in accordance with Annex V (Module B) of the applicable legislation (see note 11).

Please note:

1. Where the product is classified as category III then CE or UKCA Marking of production is reliant on current compliance with module C2 or Module D of the applicable legislation (See note 11). (Except that specifically produced to fit an individual user).
2. Full details of the scope of the certification and product(s) certified are contained within the manufacturer's technical documentation.
3. Where a translation of this certificate exists, the English language version shall be considered as the authoritative text.
4. Certification is limited to production undertaken at the sites listed in the manufacturer's technical documentation.
5. Ongoing manufactured product shall be consistent with the product(s) certified and listed on this certificate and an EU declaration of product conformity shall be made available in accordance with the applicable legislation (See note 11)
6. The Manufacturer shall inform SATRA of any changes to the certified product or technical documentation.
7. Where results obtained during type testing are within the budget of uncertainty when compared to the pass requirement, classification or performance level, then it is the responsibility of the manufacturer to ensure that the factory production control and manufacturing tolerances are such that the product placed on the market meets with the stated requirements, classifications or performance levels.
8. This certificate shall be kept together with the relevant technical documentation in a safe place by the client named on this certificate. Production of this certificate and other documentation may be required by a representative of the EC member state, or UK government.
9. This certificate relates only to the condition of the testable items at the time of the certification procedure and is subject to the expiry date shown.
10. SATRA reserves the right to withdraw this certificate if it is found that a condition of manufacture, design, materials or packaging have been changed and therefore no longer comply with the requirements of the applicable legislation (See note 11).
11. These terms and conditions shall apply to the requirements set out in Regulation (EU) 2016/425 of the European Parliament and of the council of 9th March 2016 on personal protective equipment or to UK legislation relating to UKCA Marking as defined within the issued certificate.

CE Declaration of Conformity
In accordance with Regulation (EU) 2016/425 of the European Parliamant and of the Council of 09 March 2016 Annex IX

CE Declaration of Conformity No. 173

Personal Protective Equipment
Nitril® StellarGrip orange, nitrile examination glove, powder-free, latex-free, non-sterile, colour orange, REF 1291, sizes: S-XXL (1291S, 1291M, 1291L, 1291XL, 1291XXL)
Nitril® StellarGrip black, nitrile examination glove, powder-free, latex-free, non-sterile, colour black, REF 1292, sizes: S-XXL (1292S, 1292M, 1292L, 1292XL, 1292XXL)

Name and Address of the Manufacturer

Meditrade GmbH
Medipark 1
83088 Kiefersfelden
Germany

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Object of the Declaration

The object of the declaration described above is in conformity with the relevant Union harmonisation legislation:

- EN ISO 374-1:2016/Type B
- EN ISO 374-5:2016,
- Regulation (EU) 2016/425
- EN ISO 24120:2020

The notified body (2777, SATRA) carried out the EU type examination and issued the EU type examination certificate (2777/11516-04/E03-01, valid until 08.11.2023). The PPE is subject to the following conformity assessment procedure by the notified body (2777, SATRA): Conformity to type based on quality assurance of the production process (module C2) according to Annex VII.

Kiefersfelden, 24.01.2023

Martin Unterberg
Regulatory Affairs/ Quality Management

EU-Konformitätserklärung

Gemäß Verordnung (EU) 2016/425 des Europäischen Parlaments und des Rates vom 09. März 2016 Anhang IX

EU-Konformitätserklärung Nr. 173

Persönliche Schutzausrüstung

Nitril® StellarGrip orange, Untersuchungshandschuh aus Nitril, puderfrei, unsteril, Farbe orange, REF 1291, Größen: S-XXL (1291S, 1291M, 1291L, 1291XL, 1291XXL)
Nitril® StellarGrip black, Untersuchungshandschuh aus Nitril, puderfrei, unsteril, Farbe schwarz, REF 1292, Größen: S-XXL (1292S, 1292M, 1292L, 1292XL, 1292XXL)

Name und Anschrift des Herstellers

Meditrade GmbH
Medipark 1
83088 Kiefersfelden
Germany

Die alleinige Verantwortung für die Ausstellung dieser Konformitätserklärung trägt der Hersteller.

Gegenstand der Erklärung

Diese Produkte werden von der europäischen PSA-Verordnung 2016/425 als persönliche Schutzausrüstung (PSA) der Kategorie III eingestuft und entsprechen nachweislich dieser Verordnung durch die harmonisierten europäischen Normen:

- EN ISO 374-1:2016+A1:2018/Typ B
- EN ISO 374-5:2016,
- EN ISO 21420:2020

Die notifizierte Stelle (2777, SATRA) hat die EU-Baumusterprüfung durchgeführt und die EU-Baumusterprüfbescheinigung (2777/11516-04/E03-01, gültig bis 08.11.2023) ausgestellt. Die PSA unterliegt folgendem Konformitätsbewertungsverfahren durch die notifizierte Stelle (2777, SATRA): Konformität mit dem Baumuster auf der Grundlage einer Qualitätssicherung bezogen auf den Produktionsprozess (Modul C2) gemäß Anhang VII.

Kiefersfelden, den 24.01.2023

Martin Unterberg
Regulatory Affairs/ Quality Management

VERORDNUNG (EU) 2016/425 DES EUROPÄISCHEN PARLAMENTS UND DES RATES
vom 9. März 2016 Anhang IX

Sicherheitsinformation / Safety Instruction / information sur la sécurité / informazioni sulla sicurezza

Deutsch	English	Francais	Italiano
1. Diese Information macht keine Angaben zur tatsächlichen Schutzdauer am Arbeitsplatz und zur Unterscheidung von Gemischen und reinen Chemikalien. 2. Der Widerstand gegen Chemikalien wurde unter Laborbedingungen an Proben beurteilt, die lediglich von der Handinnenfläche entnommen wurden (außer ist der Fall, bei dem der Handschuh 400 mm oder länger ist – in diesem Fall wird ebenfalls die Stulpe getestet) und bezieht sich ausschließlich auf die geprüften Chemikalien. Er kann anders sein, wenn die Chemikalie in einem Gemisch verwendet wird. Der Durchdringungswiderstand wurde unter Laborbedingungen getestet und bezieht sich ausschließlich auf die getesteten Proben. 3. Es wird eine Überprüfung empfohlen, ob die Handschuhe für die vorgesehene Verwendung geeignet sind, da die Bedingungen am Arbeitsplatz in Abhängigkeit von Temperatur, Abrieb und Degradation von denen der Typprüfung abweichen können. 4. Wurden Schutzhandschuhe bereits verwendet, können sie aufgrund von Veränderungen ihrer physikalischen Eigenschaften geringeren Widerstand gegen gefährliche Chemikalien bieten. Durch bei Berührung verursachte Degradation, Bewegungen, Fadenziehen, Reibung usw. kann die tatsächliche Anwendungszeit wesentlich reduziert werden. Bei aggressiven Chemikalien kann die Degradation der wichtigste Faktor sein, der bei der Auswahl von gegen Chemikalien beständigen Handschuhen zu berücksichtigen ist. 5. Vor der Anwendung sind die Handschuhe auf jegliche Fehler oder Mängel zu prüfen. 6. Die Entsorgung ist abhängig von der vorherigen Verwendung, nationaler Gegebenheiten und der Kontaminationsquelle.	1. This information does not reflect the actual duration of protection in the workplace and the difference between mixtures and pure chemicals. 2. The chemical resistance has been assessed under laboratory conditions from samples taken from the palm only (except in cases where the glove is equal to or over 400mm - where the cuff is tested also) and relates on y to the chemical tested. It can be different if the chemical is used in a mixture. The penetration resistance has been tested under laboratory conditions and refers exclusively to the samples tested. 3. It is recommended to check that the gloves are suitable for the intended use because the conditions at the workplace may differ from the type test depending on temperature, abrasion and degradation. 4. When used, protective gloves may provide less resistance to the dangerous chemical due to changes in the physical properties. Movements, snagging, rubbing, degradation caused by the chemical contact etc. may reduce the actual use time significantly. For corrosive chemicals, degradation can be the most important factor to consider in selection of chemical resistant Gloves. 5. Before usage, inspect the gloves for any defects or imperfections. 6. Disposal depends on previous use, national conditions and the source of contamination.	1. Ces informations ne reflètent pas la durée réelle de la protection sur le lieu de travail et la différence entre les mélanges et les produits chimiques purs. 2. La résistance à la pénétration et aux produits chimiques a été évaluée dans des conditions de laboratoire à partir d'échantillons prélevés sur la paume uniquement (sauf dans les cas où le gant est égal ou supérieur à 400 mm - où la manchette est également testée) et se rapporte au produit chimique testé. 3. Il est recommandé de vérifier que les gants sont adaptés à l'utilisation prévue car les conditions sur le lieu de travail peuvent différer de l'essai de type en fonction de la température, de l'abrasion et de la dégradation. 4. Lorsqu'ils sont utilisés, les gants de protection peuvent offrir une moindre résistance au produit chimique dangereux en raison des modifications de leurs propriétés physiques. Les mouvements, les accrochages, les frottements, la dégradation causée par le contact chimique, etc. peuvent réduire considérablement la durée d'utilisation réelle. Pour les produits chimiques corrosifs, la dégradation peut être le facteur le plus important à prendre en compte dans le choix de gants résistants aux produits chimiques. 5. Avant l'utilisation, inspectez les gants pour détecter tout défaut ou imperfection. 6. L'élimination dépend de l'utilisation précédente, des conditions nationales et de la source de contamination.	1. Queste informazioni non riflettono l'effettiva durata della protezione sul posto di lavoro e la differenza tra miscele e sostanze chimiche pure. 2. La penetrazione e la resistenza chimica sono state valutate in condizioni di laboratorio su campioni prelevati solo dal palmo (tranne nei casi in cui il guanto è uguale o superiore a 400 mm - dove viene testato anche il polsino) e si riferiscono alla sostanza chimica testata. Può essere diversa se la sostanza chimica è utilizzata in una miscela. 3. Si raccomanda di verificare che i guanti siano adatti all'uso previsto perché le condizioni sul posto di lavoro possono differire dalla prova di tipo in funzione della temperatura, dell'abrasione e della degradazione. 4. Quando vengono utilizzati, i guanti protettivi possono offrire una minore resistenza alla sostanza chimica pericolosa a causa dei cambiamenti delle proprietà fisiche. Movimenti, strappi, sfregamenti, degrado causato dal contatto chimico ecc. possono ridurre notevolmente il tempo di utilizzo effettivo. Per i prodotti chimici corrosivi, la degradazione può essere il fattore più importante da considerare nella selezione dei guanti resistenti ai prodotti chimici. 5. Prima dell'uso, ispezionare i guanti per individuare eventuali difetti o imperfezioni. 6. Lo smaltimento dipende dall'uso precedente, dalle condizioni nazionali e dalla fonte di contaminazione.

Issued to:

Meditrade GmbH
Medipark 1
83088 Kiefersfelden
Germany

Notified Body: 2777

SATRA customer number: P1772

EU Type-Examination Certificate

Certificate number: 2777/11516-04/E03-01

This EU Type-Examination Certificate covers the following product group(s) supported by testing to the relevant standards/technical specifications and examination of the technical file documentation. It has been issued Under Module B of Regulation 2016/425 on personal protective equipment. This product group has been shown to satisfy the applicable essential health and safety requirements as a Category III product.

Product Reference

Orange:
Nitril® StellarGrip REF 1291(S-XXL)
Black:
Nitril® StellarGrip REF 1292(S-XXL)

Description

Five fingered 8.0mil ambidextrous nitrile examination gloves with diamond patterned finish and beaded cuff.

Size:

S:6-7
M:7-8
L: 8-9
XL:9-10
XXL:10-11

Classification:

EN ISO 374-1:2016 / Type B	Level	EN 374-4:2013 Degradation %
37% Formaldehyde (T)	4	-6.4
96% Sulphuric acid (L)	1	100.0
40% Sodium hydroxide (K)	6	-40.8
25% Ammonium hydroxide (O)	1	-6.5
n-Heptane (J)	2	26.8

EN ISO 374-5:2016	
Protection against bacteria and fungi	Pass
Protection against viruses	Pass

Standards/Technical specifications applied:
EN ISO 374-1:2016; EN ISO 21420:2020; EN ISO 374-5:2016

Technical reports/Approval documents:
SATRA: SPC0247907/1628/SMcD/A, CHM0256738/1717/SMcD, SPC0247907/1628/1, PRC0261193/1733/EN/B, PRC0261193/1733/EN/A, CHM0256736/1717/SMcD, SPC0265716/1804/4 Issue 3, SPC0265716/1804/1, CHM0292474/2002/LC, CHM0301626/2034/JS, CHM03120098/2116/JH/B, CHM0311831/2115/LC

Signed on behalf of SATRA: Jacque Glasspool

Date of issue: 21/12/2022
Expiry date: 08/11/2023

TERMS AND CONDITIONS

The following conditions apply in addition to SATRA's standard terms and conditions of business and those given in the current certification agreement. This certificate has been issued in accordance with Annex V (Module B) of the applicable legislation (see note 11).

Please note:

1. Where the product is classified as category III then CE or UKCA Marking of production is reliant on current compliance with module C2 or Module D of the applicable legislation (See note 11). (Except that specifically produced to fit an individual user).
2. Full details of the scope of the certification and product(s) certified are contained within the manufacturer's technical documentation.
3. Where a translation of this certificate exists, the English language version shall be considered as the authoritative text.
4. Certification is limited to production undertaken at the sites listed in the manufacturer's technical documentation.
5. Ongoing manufactured product shall be consistent with the product(s) certified and listed on this certificate and an EU declaration of product conformity shall be made available in accordance with the applicable legislation (See note 11)
6. The Manufacturer shall inform SATRA of any changes to the certified product or technical documentation.
7. Where results obtained during type testing are within the budget of uncertainty when compared to the pass requirement, classification or performance level, then it is the responsibility of the manufacturer to ensure that the factory production control and manufacturing tolerances are such that the product placed on the market meets with the stated requirements, classifications or performance levels.
8. This certificate shall be kept together with the relevant technical documentation in a safe place by the client named on this certificate. Production of this certificate and other documentation may be required by a representative of the EC member state, or UK government.
9. This certificate relates only to the condition of the testable items at the time of the certification procedure and is subject to the expiry date shown.
10. SATRA reserves the right to withdraw this certificate if it is found that a condition of manufacture, design, materials or packaging have been changed and therefore no longer comply with the requirements of the applicable legislation (See note 11).
11. These terms and conditions shall apply to the requirements set out in Regulation (EU) 2016/425 of the European Parliament and of the council of 9th March 2016 on personal protective equipment or to UK legislation relating to UKCA Marking as defined within the issued certificate.