Issued to: Meditrade GmbH
Medipark 1
83088 Kiefersfelden
Germany

Notified Body: 2777 SATRA customer number: P1626

EU Type-Examination Certificate

Certificate number: 2777/12003-02/E05-01

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:	**Description:**
1286XS, 1286S, 1286M, 1286L, 1286XL	Nitrile Powder Free Gloves, Non-sterile
Nitril® Best Gen®	Available in Warm Blue, Black, Ivory white, Purple and CF Blue

Sizes: 6/XS to 10/XL

Classification:

EN ISO 374-1: 2016 (Type B)	**Level**	**EN 374-4: 2013 % Degradation**
40% Sodium Hydroxide (K)	6	-11.5
30% Hydrogen Peroxide (P)	4	19.1
37% Formaldehyde (T)	6	27.2

EN ISO 374-5: 2016	**Level**
Protection against bacteria & fungi	Pass
Protection against viruses	Pass

Standards/Technical specifications applied:
EN 420: 2003+A1: 2009; EN ISO 374-1:2016; EN ISO 374-5:2016

Technical reports/Approval documents:
SATRA: CHM0244415/1614/EN, CHM0274839/1835/LH/A, CHM0274839/1835/LH/B, CHM0274839/1835/LH/C, SPC0244648/1615, CHM0294876/2006/LC/Issue 2

Signed on behalf of SATRA: Quincey Brown

Date of issue: 29/04/2021
Expiry date: 21/02/2024

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.

EU-Konformitätserklärung Nr. 136

Persönliche Schutzausrüstung
Nitril® BestGen, Untersuchungshandschuh aus Nitril, puderfrei, latexfrei, unsteril, Farbe blau, REF1286, Größen: XS, 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 420:2003+A1:2009
- EN ISO 374-1:2016/Typ B
- EN ISO 374-5:2016,
- Verordnung (EU) 2016/425

Die notifizierte Stelle (SATRA, 2777) hat die EU-Baumusterprüfung durchgeführt und die EU-Baumusterprüfbescheinigung (2777/12003-02/02/E05-01, gültig bis 21.02.2024) ausgestellt. Die PSA unterliegt folgendem Konformitätsbewertungsverfahren durch die notifizierte Stelle (SATRA, 2777): Konformität mit dem Baumuster auf der Grundlage einer Qualitätssicherung bezogen auf den Produktionsprozess (Modul C2) gemäß Anhang VII.

Kiefersfelden, den 22.11.2021

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Martin Unterberg
Regulatory Affairs/ Quality Management

EU Declaration of Conformity No. 136

Personal Protective Equipment
Nitril® BestGen, nitrile examination glove, powder-free, latex-free, non-sterile, colour blue, REF1282, sizes: XS, 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/Type B
- EN ISO 374-5:2016
- EN 420:2003+A1:2009
- Regulation (EU) 2016/425

The notified body (SATRA, 2777) carried out the EU type examination and issued the EU type examination certificate (2777/12003-02/E05-01, valid until 21.02.2024). 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, 22.11.2021

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Martin Unterberg
Regulatory Affairs/ Quality Management

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 (ausgenommen ist der Fall, bei dem der Handschuh- 400mm 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. 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 di Degradation der wichtigste Faktor sein, der bei der Auswahl von gegen Chemikalien beständigen Handschuhen zu berücksichtigen ist. Die Penetration wurde unter Laborbedingungen bewertet und bezieht sich nur auf die geprüften Proben. 5. Vor der Anwendung sind die Handschuhe auf jegliche Fehler oder Mängel zu prüfen.	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 ls equal to or over 400mm - where the cuff is tested also) and relates on y to the chemical tested. lt can be different if the chemical is used in a mixture. 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. The penetration resistance has been assessed under laboratory conditions and relates only to the tested specimen. 5. Before usage, inspect the gloves for any defects or imperfections.	1. Cette information ne donne aucune indication sur la durée de protection effective au poste de travail ni sur la distinction entre les mélanges et les produits chimiques purs. 2. La résistance aux produits chimiques a été évaluée dans des conditions de laboratoire sur des échantillons qui ont simplement été prélevés dans la paume de la main (à l'exception du cas où le gant avait une longueur de 400mm ou plus – auquel cas le revers est également testé) et fait uniquement référence aux produits chimiques testés. Il peut en aller autrement si les produits chimiques sont utilisés dans un mélange. 3. Il est recommandé de vérifier si les gants conviennent à l'usage prévu, du fait que les conditions au poste de travail peuvent s'écarter du contrôle de type en fonction de la température, du frottement et de la dégradation. 4. Si des gants de protection ont déjà été utilisés, il est possible qu'ils n'offrent qu'une faible résistance aux produits chimiques dangereux du fait d'un changement de leurs propriétés physiques. Les dégradations, mouvements, tirages de fils, frottements etc. consécutifs au contact avec des produits chimiques peut considérablement réduire la durée d'utilisation effective. Dans le cas de produits chimiques agressifs, la dégradation peut être le facteur le plus important à prendre en compte lors de la sélection de gants résistant aux produits chimiques. La pénétration a été évaluée sous conditions de laboratoire et se réfère uniquement aux échantillons testés. 5. Les gants doivent être contrôlés quant à la présence de défauts ou de carences quelconques avant utilisation.	1. Questa informazione non fornisce indicazioni riguardo all'effettiva durata della protezione sul luogo di lavoro e riguardo alla distinzione tra miscele e sostanze chimiche pure. 2. La resistenza alle sostanze chimiche è stata valutata in condizioni di laboratorio, sulla base di campioni prelevati soltanto dal palmo della mano (salvo che i guanti siano lunghi 400 mm o più, nel qual caso viene testato anche il risvolto), e si riferisce esclusivamente alle sostanze chimiche testate. Può essere diversa se la sostanza chimica viene utilizzata in una miscela. 3. Si raccomanda di accertarsi che i guanti siano adatti all'utilizzo previsto, poiché le condizioni sul luogo di lavoro possono differire da quelle del controllo standard per via della temperatura, dell'abrasione e della degradazione. 4. Se i guanti protettivi sono già stati utilizzati, questi, a causa di cambiamenti delle loro proprietà fisiche, potrebbero offrire una ridotta resistenza alle sostanze chimiche pericolose. L'effettiva durata di utilizzazione può essere considerevolmente ridotta in conseguenza degli attriti, degli sfilacciamenti, dei movimenti, della degradazione causata dal contatto con sostanze chimiche, ecc. In presenza di sostanze chimiche aggressive, la degradazione può essere il fattore da tenere in maggiore considerazione nella scelta di guanti resistenti alle sostanze chimiche. La penetrazione è stata valutata in condizioni di laboratorio, e si riferisce solo ai campioni esaminati. 5. Prima dell'utilizzo, i guanti devono essere controllati per escludere la presenza di qualsiasi difetto o danneggiamento.