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.

EU-Konformitätserklärung Nr. 160

Persönliche Schutzausrüstung

Nitril Sensory white, Untersuchungshandschuh aus Nitril, puderfrei, latexfrei, unsteril, Farbe weiß, REF2280, 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
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. 160

Personal Protective Equipment
Nitril Sensory white, nitrile examination glove, powder-free, latex-free, non-sterile, colour white, REF2280, 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