



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/E30-01

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:

Centramed Nitril
Untersuchungshandschuhe
9510857(S) – 9510860(XL)

Description:

Disposable Nitrile Gloves (Non-sterile).
Colour: Blue

Sizes:

6 – 6.5 /S
7 – 7.5 /M
8 – 8.5 / L
9 – 9.5 /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: 23/05/2022
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

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

EU-Konformitätserklärung Nr. 018

Persönliche Schutzausrüstung

Centramed Nitril Untersuchungshandschuhe
Untersuchungshandschuh aus Nitril, puderfrei, latexfrei, unsteril, Farbe blau,
REF 951 08, Größen: S, M, L, XL (951 0857, 951 0858, 951 0859, 951 0860)

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/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 (2777/14815-03/E30-01, gültig bis
20.07.2025) 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 24.05.2022



Martin Unterberg
Regulatory Affairs/ Quality Management



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

CE Declaration of Conformity No. 018

Personal Protective Equipment

Centramed Nitril Untersuchungshandschuhe

nitrile examination glove, powder-free, latex-free, non-sterile, colour blue

REF 951 08, sizes: S, M, L, XL (951 0857, 951 0858, 951 0859, 951 0860)

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/E30-01, 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, 24.05.2022

Martin Unterberg
Regulatory Affairs/ Quality Management

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

Deutsch	English	Français	Italiano
<p>1. Diese Information macht keine Angaben zur tatsächlichen Schutzdauer am Arbeitsplatz und zur Unterscheidung von Gemischen und reinen Chemikalien.</p> <p>2. Die Penetration und der Widerstand gegen Chemikalien wurde unter Laborbedingungen an Proben beurteilt, die lediglich von der Handinnenfläche entnommen wurden (außer im 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.</p> <p>3. Es wird eine Überprüfung empfohlen, ob die Handschuhe für die vorgesehene Verwendung geeignet sind, da die Bedingungen am Arbeitsplatz in Abhängigkeit von Temperatur, Antrieb und Degradation von denen der Typprüfung abweichen können.</p> <p>4. Würden 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.</p> <p>5. Vor der Anwendung sind die Handschuhe auf jegliche Fehler oder Mängel zu prüfen. Die Entsorgung ist abhängig von der vorherigen Verwendung, nationaler Gegebenheiten und der Kontaminationsquelle.</p>	<p>1. This information does not reflect the actual duration of protection in the workplace and the difference between mixtures and pure chemicals.</p> <p>2. The penetration and 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. 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.</p> <p>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.</p> <p>5. Before usage, inspect the gloves for any defects or imperfections.</p> <p>6. Disposal depends on previous use, national conditions and the source of contamination.</p>	<p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>5. Avant l'utilisation, inspectez les gants pour détecter tout défaut ou imperfection.</p> <p>6. L'élimination dépend de l'utilisation précédente, des conditions nationales et de la source de contamination.</p>	<p>1. Queste informazioni non riflettono l'effettiva durata della protezione sul posto di lavoro e la differenza tra miscele e sostanze chimiche pure.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>5. Prima dell'uso, ispezionare i guanti per individuare eventuali difetti o imperfezioni.</p> <p>6. Lo smaltimento dipende dall'uso precedente, dalle condizioni nazionali e dalla fonte di contaminazione.</p>



User information

Version: 2022-05-19

1. Product Information	
Name:	Centramed Nitril Untersuchungshandschuhe
REF:	951 0857, 951 0858, 951 0859, 951 0860
Sizes:	S, M, L, XL
Colour:	blue

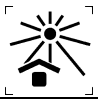


2. Instructions for storage, use, cleaning, maintenance, inspection and disinfecting

2.1 Use

The non-sterile examinations gloves are intended for the protection from contamination of patients and user. For single use only.



Donning	<ol style="list-style-type: none"> 1: Wash and dry hands thoroughly. Remove all hand and wrist jewellery. 2: Touch only the edge of the inside of the glove. 3: Carefully pull the glove loosely over the finger and insert the thumb of the other hand loosely into the glove on the underside of the wrist. 4 + 5: now grasp the inside thumb on the outside of the glove with the other fingers and pull the glove over the palm towards the crook of the elbow without stretching it too much. 6: Repeat steps 2-5 with the other hand.
Doffing	<ol style="list-style-type: none"> 1: Loosen the glove at the fingertips and wrist. 2: Turn the glove inside out and remove it. 3: The gloved hand holds and disposes of the glove. 4 + 5: When removing the glove, the naked hand reaches into the palm of the other hand, lifts the glove and then, starting at the cuff, pulls it off completely and holds it inside 6: Disposal depends on previous use. Contaminated gloves must be disposed of according to the instructions of the source of contamination.

2.2 Storage

	protect from direct sunlight
	Store in a dry place
	Storage temperature: 5 °C – 35 °C

Wichtiger Hinweis: Nichtbeachtung der Informationen, insbesondere zur Verwendung, Verträglichkeit und Beständigkeit kann zu Personen- und Sachschäden führen. Die Meditrade GmbH übernimmt keine Haftung für falschen Einsatz der Produkte. Es handelt sich um ein Produkt zum Einmalgebrauch – Materialveränderungen / Infektionsrisiken können bei Mehrfachgebrauch nicht ausgeschlossen werden. Die hier enthaltenen Informationen entsprechen dem Zeitpunkt des letzten Änderungsstands. Irrtümer, Druckfehler sowie Änderungen behalten wir uns vor. Holen Sie im Zweifelsfall fachkundigen Rat ein. Die jeweils aktuellen Produktinformationen finden Sie auf unserer Homepage www.meditrade.de.

Important Note: Non-observance of the information, especially in view of use, compatibility and durability may lead to damage to persons and / or material. Meditrade does not take any liability in case of improper use. This is a single use product – changes in material / infection risk cannot be excluded in case of multiple use. All information included correspond with the last document amendment date. Errors, literal mistakes and changes expected. In case of doubt please seek expert advice. Please find any up-dated product information on our homepage www.meditrade.de.

2.3 Shelf life	
	Manufacturing date: printed as YYYY-MM
	Shelf life: 5 years

2.4 Inspection
<p>Only use protective gloves for the intended use and in the correct size.</p> <p>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.</p> <p>Before use, check the gloves for any faults or defects.</p>

2.5 Cleaning
NA – this product is for single use only.

2.6 Maintenance
NA – this product is for single use only.

2.7 Disinfecting
NA – this product is for single use only.


3. Protection
<p>These products are classed as Category III Personal Protective Equipment (PPE) by the European PPE REGULATION 2016/425 and have been shown to comply with this Regulation through the harmonised European Standard(s): EN ISO 21420:2020, EN ISO 374-1:2016+A1:2018, EN ISO 374-5:2016</p>

1. Performance			
Chemical permeation (EN ISO 374-1:2016)	Level	Mean degradation % (EN ISO 374-2019)	
40% sodium hydroxide (K)	6	- 68,1	Degradation levels indicate the change in puncture resistance of the glove after exposure to the chemical tested.
30 % hydrogen peroxide (P)	2	30,5	
37 % formaldehyde (T)	5	9,5	

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EN ISO 374-1:2016 /
TYPE B



KTP

EN ISO 374-1:2016 Classification of permeation performance level	
Measured breakthrough time (min)	Permeation performance level
> 10	1
> 30	2
> 60	3
> 120	4
> 240	5
> 480	6

EN ISO 374-5:2016



VIRUS

Resistance against bacteria and fungi – PASSED
Resistance against viruses - PASSED

5. Warnings

This information does not reflect the actual duration of protection in the workplace and the difference between mixtures and pure chemicals.

The penetration and 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 to the chemical tested. It can be different if the chemical is used in a mixture.

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.

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.

Before usage, inspect the gloves for any defects or imperfections.

The glove does not contain any substances that are known to cause allergies.

6. EU declaration of conformity

Declaration of conformity and information in German and English: www.meditrade.de/3K3DFV

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7. Manufacturer



Meditrade GmbH / Mediark1 / 83088 Kiefersfelden / Germany / www.meditrade.de

8. Notified Body



EU type examination and ongoing conformity by notified body: **2777**

SATRA Technology Europe Ltd
Bracetown Business Park
Clonee, D15 YN2P, Ireland

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