



## Nitril-Handschuhe CELOS Glove 1.10

pure<sup>11</sup>-Nr.: 05050, Hersteller: Distributor pure<sup>11</sup>

### Zusammenfassung

- Neue pure11-Artikelnummer (ab 01.07.2023): 1105050
- Material: Nitril
- Beidhändig tragbar
- Puderfrei
- Latexfrei
- AQL-Wert (Acceptable Quality Level): 1.5
- Texturierte Fingerspitzen
- Vulkanisationsbeschleunigerfrei
- Einzigartige Passform und exzellentes Fingerspitzengefühl
- Reduziertes Allergierisiko
- Niedrige Partikel- und Ionenrückstandswerte
- Nachgereinigt mit 0.2 µm gefiltertem DI-Wasser
- Doppelt unterverpackt

### Empfohlene Reinraumklassen

ISO  3  4  5  6  7  8  9

GMP      C  D

### Produktvarianten

**pure<sup>11</sup>-Nr.: 05050XS**

Farbe: Weiß / Größe: XS / VE: 1.000 Stück

**pure<sup>11</sup>-Nr.: 05050S**

Farbe: Weiß / Größe: S / VE: 1.000 Stück

**pure<sup>11</sup>-Nr.: 05050M**

Farbe: Weiß / Größe: M / VE: 1.000 Stück

**pure<sup>11</sup>-Nr.: 05050L**

Farbe: Weiß / Größe: L / VE: 1.000 Stück

**pure<sup>11</sup>-Nr.: 05050XL**

Farbe: Weiß / Größe: XL / VE: 1.000 Stück

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**pure<sup>11</sup>-Nr.: 05050XXL**

Farbe: Weiß / Größe: XXL / VE: 1.000 Stück

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**pure<sup>11</sup>-Nr.: 050503XL**

Farbe: Weiß / Größe: 3XL / VE: 1.000 Stück

Quelle: <https://www.pure11.de/nitril-handschuhe-celos-glove-110>

**pure<sup>11</sup> GmbH**

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## Cleanroom Nitrile CELOS® Glove 1.10

### Product information:

<i>Material</i>	100% pure Nitrile
<i>Process</i>	Laundered with 0.2 micron filtered high resistivity DI water and packed in certified clean-room environment
<i>Application</i>	Cleanroom glove with best in class fit and for highest cleanliness requirements
<i>Length</i>	300 mm
<i>Palm Thickness</i>	0.10 mm <sup>2</sup> (+/- 0.02 mm)
<i>Color</i>	Natural white
<i>Chem. Performance</i>	TYPE B, JKPT, VIRUS

### Products:

<i>Part number</i>	<i>Style</i>	<i>Size</i>	<i>Inner packing</i>	<i>Quantity per case</i>
<b>05050</b>	Unsterile	XS - 3XL	100 pcs/bag	10 bag/case

### Characteristics:

- Personal Protective Equipment - Category III
- Glove of newest generation
- Ambidextrous
- Silicone and latex free
- Unique fit and textured fingertips
- Reduced allergy risk
- High tackiness for great grip
- Without plasticizers, contain no phthalates, silicone oil and amide
- No sulphur, accelerator and zinc added during compounding process
- Cleanroom produced and packaged

### Performance parameter:

	<i>Specification</i>	<i>Unit</i>
Particle count (0.5 - 20 micron, cum)	< 1200	counts/cm <sup>2</sup>
Fluoride	< 0.01	µg/cm <sup>2</sup>
Chloride	< 0.30	µg/cm <sup>2</sup>
Nitrite	< 0.05	µg/cm <sup>2</sup>
Bromide	< 0.05	µg/cm <sup>2</sup>
Nitrate	< 0.30	µg/cm <sup>2</sup>
Phosphate	< 0.05	µg/cm <sup>2</sup>
Sulphate	< 0.05	µg/cm <sup>2</sup>
NVR (DI water)	< 3.00	µg/cm <sup>2</sup>
Surface resistivity	≤ 10 <sup>11</sup>	ohm/sq
Decay time	≤ 2.0	seconds
Tribo charge	≤ 50	volt

pure<sup>11</sup> has made every attempt to ensure the accuracy and reliability of the information provided in this datasheet. However, the information is provided "as is" without warranty of any kind. pure<sup>11</sup> does not accept any responsibility or liability for the accuracy, content, completeness, legality, or reliability of the information contained.

## Cleanroom Nitrile CELOS® Glove 1.10

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### Additional important Product information

According to the EN 21420 : 2020 test, it is confirmed that during the production of CELOS gloves 05050, none of the following chemicals are introduced into the production process, thus reducing allergic reactions

- Thirum disulfide
- Dithiocarbamates
- Mercaptobenzothiazole / MBT derivatives
- 1,3 - diphenylguanidine
- Duphenylthiourea, dibuthylthiourea
- Formaldehyde
- Bisphenol A
- Bezoisothiazolinine
- Cethylpyridinium Chloride
- Triphenyl phosphite, triphenyl phosphate, tricresyl phosphate
- Abietic acid derivatives
- Nickel

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## Cleanroom Nitrile CELOS® Glove 1.10

Parameter	Test method	Result
pH value	DIN EN 420:2010	Measured pH value: 6,4
Dangerous chemicals and micro-organisms	DIN EN 374-1 + A1:2018 DIN EN 374-5:2016	Pass
Air-Leak-Test	DIN EN 374-2:2015	Pass
Water-Leak-Test	DIN EN 374-2:2015	Pass
Permeation	DIN EN 16523-1:2015	See table below
Degradation	DIN EN 374-4:2014	See table below

### Performance Parameter

#### 1. Permeation

Test chemicals	Code	Sample 1 Breakthrough [min]	Sample 2 Breakthrough [min]	Sample 3 Breakthrough [min]
N-heptane	J	40	34	39
Hydrogen peroxide (30 %)	P	> 480	> 480	> 480
Formaldehyde (37 %)	T	89	58	36
Sodium hydroxide (40 %)	K	> 480	> 480	> 480
Ethanol (70 %)	-/-	17	14	16
2-Propanol (70 %)	-/-	34	45	33
Hydrochloric acid (30 %)	-/-	> 480	> 480	> 480
Sulfuric acid (50 %)	-/-	> 480	> 480	> 480

#### 2. Degradation

Test chemicals	Code	Degradation [%]	Standard deviation [%]
N-heptane	J	- 40,7	62,9
Hydrogen peroxide	P	31,6	6,5
Formaldehyde	T	18,8	36,4
Sodium hydroxide	K	- 24,3	32,4

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## Cleanroom Nitrile CELOS® Glove 1.10

Dear Valued Customer,

This data sheet shall give an overview of results for food contact testing of Cleanroom Nitrile CELOS® Glove 1.10. The results below reflect migration testing in according to the test specification § 31 LFGB (German Food and Feed Code).

The product complies with the total migration limit as described. According to the kind and extent of tests performed the test item meets the requirements of the test specification LFGB §31 and is therefore suitable for contact with foodstuff.

Parameter	Test method -Standard	Result
Sensory analysis	DIN 10955:2004	
smell transfer		Pass
transfer of taste		Pass
Overall migration	DIN EN 1186 ff.:2002	See table below
Overall migration, Tenax	DIN EN 1186-13:2002	See table below
Acrylonitril, migration	DIN EN 13130-3:2004	See table below
1,3-Butadiene, migration	DIN CEN / TS 13130-15:2005	See table below
Formaldehyde, content	DIN CEN / TS 13130-23:2005	See table below
Primary aromatic amines, migration	In-house method - quantification by HPLC-MS/MS	Pass
Metals, Natural or Synthetic Rubber	MS-0022823:2020	Pass
N-Nitrosamines and N-nitrosatable substances	DIN EN 12868:2017	Pass
Polycyclic aromatic hydrocarbons (PAK)	AfPS GS 2014:01 PAK:2014	Pass

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## Cleanroom Nitrile CELOS® Glove 1.10

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### Sensory analysis

	Contact medium	Pass / Fail
Smell transfer	Water	Pass
Transfer of taste	Water	Pass

The samples comply with the requirements of § 31 Para. 1 LFGB or Article 3 of Regulation (EC) 1935/2004.

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### Overall migration into Food Simulants

	Overall Migration (mg /dm <sup>2</sup> )	Pass / Fail
Acetic Acid 3%	4	Pass
Ethanol 50%	7	Pass
Tenax	<2	Pass

The samples comply with the limit value for products in contact with food according to the Consumer Goods Ordinance or Regulation (EU) No. 10/2011 and any amendments thereto.

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## Cleanroom Nitrile CELOS® Glove 1.10

### Migration of Acrylonitril and 1,3 – Butadiene

Migration Solution	Acrylonitril		1,3 - Butadiene	
	Oil	Acetic Acid 3%	Oil	Acetic Acid 3%
Results (mg/kg)	< 0,005	< 0,005	< 0,01	<0,01
Pass / Fail	Pass	Pass	Pass	Pass

The samples comply with limit value for products in contact with foodstuffs according to the German Commodity Goods Ordinance respectively Regulation (EU) No 10/2011 and amendments.

### Formaldehyde content

	Result (mg /l)	Pass / Fail
Formaldehyde	< 1	Pass

The samples comply with the requirements according to the recommendation of the BfR part XXI "Commodities based on Natural and Synthetic Rubber".

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## Cleanroom Nitrile CELOS® Glove 1.10

### Primary aromatic amines, migration

	Result (mg/kg food simulant)	Migration solution	Pass / Fail
2,5-Dichloraniline	<0,01	Acetic Acid 3 %	Pass
2,4,5-Trichloraniline	<0,01	Acetic Acid 3 %	Pass
4-Chlor-3-methoxyaniline	<0,01	Acetic Acid 3 %	Pass

### Metals / Natural or Synthetic Rubber

	Category	Result (%)	Pass / Fail	Requirement
Lead	3	< 0,001	Pass	Zinc content: Categories 1, 2 and 3 commodities max. 0,003% Special Category commodities max. 0,001%
Zinc	3	< 1	Pass	Lead impurities: Categories 1, 2 and 3 commodities max. 3.0% Special Category commodities max. 1.0%

\*Category 1-Materials intended to be put in mouth or materials for toys intended to come into contact and with prolonged contact with the skin (longer than 30 s).

\*Category 2-Materials not covered by category 1 with foreseeable contact to skin for longer than 30 seconds (longer term skin contact) or repeated short term skin contact.

\*Category 3-Materials not covered by category 1 or 2 with foreseeable contact to skin up to 30 seconds (short term skin contact).

The samples comply with the requirement according to BfR recommendation XXI "Consumer goods based on natural and synthetic rubber".

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**Z E R T I F I K A T**  
**EU-Baumusterprüfbescheinigung**  
**Verordnung 2016/425/EU**  
**Persönliche Schutzausrüstung**



**Registrier Nr.:** BP 60157843 0001

**Bericht Nr.:** 60442482 003

**Inhaber:** Pure11 GmbH  
Bavariafilmplatz 7  
82031 Grünwald  
Deutschland

**Produkt:** Schutzhandschuhe gegen Chemikalien und Mikroorganismen  
gemäß EN ISO 374-1+A1:2018 und EN ISO 374-5:2016

**Identifikation:** Nitrilhandschuhe CELOS® Glove 1.10 , puderfrei, weiß  
Produktcode: 05050+Größe: XS(5,5) - 3XL(11,0-11,5)  
Material: Nitril, Dicke ca. 0,1 mm  
chem. Beständigkeit: Typ B, VIRUS  
J- n-Heptan Klasse 2, K- 40%Natriumhydroxid Klasse 6  
T-37%Formaldehyd Klasse 2, P- 30%Wasserstoffperoxid Klasse 6  
- PSA Kategorie III - Überwachungspflichtig Modul C2 -

Die EU-Baumusterbescheinigung bezieht sich auf das o.g. Produkt. Es wird bescheinigt, dass das Produkt den grundlegenden Anforderungen nach Anhang II der Verordnung 2016/425/EU entspricht. Das Zertifikat stellt kein allgemein gültiges Urteil über die Serienfertigung des Produktes dar und berechtigt nicht zur Nutzung eines TÜV Rheinland Prüfzeichens. Der Inhaber ist berechtigt, diese Bescheinigung im Rahmen seiner EU-Konformitätserklärung gemäß Anhang IX zu verwenden. Bei Produkten der Kategorie III darf diese Bescheinigung nur in Verbindung mit einem der in Artikel 19 Buchstabe c) der Verordnung (EU) 2016/425 genannten Konformitätsbewertungsverfahren verwendet werden.

Gültig bis: 05.08.2026

Benannte Stelle

Datum 06.08.2021

Dipl.-Ing. C. Albrecht



**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**  
Benannt durch die Zentralstelle der Länder für Sicherheitstechnik (ZLS).

Notifiziert unter Nr. **0197** bei der Kommission der Europäischen Gemeinschaft.

Die CE-Kennzeichnung darf bei Einhaltung aller zutreffenden EU-Richtlinien angebracht werden.

**C E R T I F I C A T E**  
**EU Type-Examination Certificate**  
**Regulation 2016/425/EU**  
**Personal Protective Equipment**



**Registration No.:** BP 60157843 0001

**Report No.:** 60442482 003

**Holder:** Pure11 GmbH  
Bavariafilmplatz 7  
82031 Grünwald  
Deutschland

**Product:** Protective gloves against chemicals and micro-organisms  
according to EN ISO 374-1+A1:2018 and EN ISO 374-5:2016

**Identification:** Nitrile gloves CELOS® Glove 1.10 , powder free, white  
Productcode: 05050+size: XS(5,5) - 3XL(11,0-11,5)  
Material: nitrile, thickness ca. 0,1 mm  
chemical performance: Type B, VIRUS  
J- n-Heptane class 2, K- 40%sodium hydroxide class 6  
T- 37%Formaldehyde class 2, P-3 0%Hydrogen peroxide class 6  
- PPE Category III - obligatory monitoring module C2 -

The EU type-examination certificate refers to the above mentioned product. This is to certify that the product complies with the essential requirements of Annex II of the regulation 2016/425/EU. This certificate does not imply assessment of the production of the product and does not permit the use of a TÜV Rheinland mark of conformity. The holder is entitled to use this certificate in connection with the declaration of conformity in accordance with Annex IX. In case of category III products this certificate shall only be used in conjunction with one of the conformity assessment procedures referred to in point (c) of Article 19 of the Regulation 2016/425 EU.

**Valid till:** 05.08.2026

**Date** 06.08.2021

Notified Body



Dipl.-Ing. C. Albrecht

**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**  
Notified by Zentralstelle der Länder für Sicherheitstechnik (ZLS).

Notified under No. **0197** to the EC Commission.

CE The CE marking may be used if all relevant and effective EC Directives are complied with. CE