



## Empfohlene Reinraumklassen

ISO 4|5|6|7|8|9

GMP A/B|C|D



## Nitril-Handschuhe CELOS Glove 2.20

pure<sup>11</sup>-Nr.: 1130310, Marke: CELOS

### Eigenschaften

- Steril
- Marke: CELOS
- Handschuhtyp: Dünnsfilm
- Länge in cm: 31 cm
- Chemikalienbeständigkeit - Typ: Typ B
- Puderfrei
- Material: Nitril
- Texturierte Fingerspitzen
- Zytostatikageeignet
- Silikonfrei
- Vulkanisationsbeschleunigerfrei
- Verpackungsform: paarweise verpackt
- Antistatisch
- AQL (Acceptable Quality Level)-Wert: 0,65
- Chemikalienbeständig gegen Isopropanol (70%): Level 2 (30-60min)
- Im Reinraum hergestellt
- Länge in Inches: 12 In
- Latexfrei
- Niedrigen Endotoxin-Gehalt

- Oberflächenbeschaffenheit: griffig
- Rollrand
- Schutz vor Blut und Körpersekreten ISO 16604:2004
- Passform Hand: handspezifisch
- Viren-/Mikroorganismenschutz EN ISO 374-5:2016
- Wandstärke Mittelfinger in mm: 0,14 mm

### **Material**

- Nitril

### **Verpackung**

- 200PAAR

## Produktvarianten

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**pure<sup>11</sup>-Nr.: 1130310WH6\_5, Nitril-Handschuhe CELOS Glove 2.20**

Farbe: Weiß; Größe: 6,5 / VE: 200PAAR

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**pure<sup>11</sup>-Nr.: 1130310WH10, Nitril-Handschuhe CELOS Glove 2.20**

Farbe: Weiß; Größe: 10 / VE: 200PAAR

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**pure<sup>11</sup>-Nr.: 1130310WH6, Nitril-Handschuhe CELOS Glove 2.20**

Farbe: Weiß; Größe: 6 / VE: 200PAAR

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**pure<sup>11</sup>-Nr.: 1130310WH7, Nitril-Handschuhe CELOS Glove 2.20**

Farbe: Weiß; Größe: 7 / VE: 200PAAR

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**pure<sup>11</sup>-Nr.: 1130310WH7\_5, Nitril-Handschuhe CELOS Glove 2.20**

Farbe: Weiß; Größe: 7,5 / VE: 200PAAR

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**pure<sup>11</sup>-Nr.: 1130310WH8, Nitril-Handschuhe CELOS Glove 2.20**

Farbe: Weiß; Größe: 8 / VE: 200PAAR

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**pure<sup>11</sup>-Nr.: 1130310WH8\_5, Nitril-Handschuhe CELOS Glove 2.20**

Farbe: Weiß; Größe: 8,5 / VE: 200PAAR

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**pure<sup>11</sup>-Nr.: 1130310WH9, Nitril-Handschuhe CELOS Glove 2.20**

Farbe: Weiß; Größe: 9 / VE: 200PAAR

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# CELOS Nitrile Glove 2.20



CLEANROOM PRODUCTS | PERSONNEL



## RECOMMENDED CLEANROOM CLASSES

|     |   |     |   |   |   |   |   |
|-----|---|-----|---|---|---|---|---|
| ISO | 3 | 4   | 5 | 6 | 7 | 8 | 9 |
| GMP |   | A/B |   |   | C | D |   |

## PRODUCT INFORMATION

|                     |                                                     |
|---------------------|-----------------------------------------------------|
| MATERIAL            | 100 % pure Nitrile                                  |
| DESIGN              | Beaded cuff and micro-textured throughout the glove |
| APPLICATION         | Sterile cleanroom glove for highest requirements    |
| COLOR               | White                                               |
| CUFF THICKNESS      | 0.10 mm (+/-0.01 mm)                                |
| PALM THICKNESS      | 0.13 mm (+/-0.01 mm)                                |
| THICKNESS AT FINGER | 0.15 mm (+/-0.01 mm)                                |
| LENGTH              | Min. 310 mm                                         |
| AQL                 | 0.65                                                |

# CELOS Nitrile Glove 2.20

## PRODUCTS

| PART NUMBER    | VARIANT      | SIZE | STYLE   | INNER PACKAGING                 | QUANTITY PER CASE        |
|----------------|--------------|------|---------|---------------------------------|--------------------------|
| <b>1130310</b> | <b>WH6</b>   | 6    | Sterile | 1 pair/1 peel pouch             | 4 intermediate bags/LDPE |
|                | <b>WH6_5</b> | 6.5  |         | 10 peel pouches/1 outer bag     | carton liner and case    |
|                | <b>WH7</b>   | 7    |         | 5 outer bags/1 intermediate bag | 200 pairs/case           |
|                | <b>WH7_5</b> | 7.5  |         |                                 |                          |
|                | <b>WH8</b>   | 8    |         |                                 |                          |
|                | <b>WH8_5</b> | 8.5  |         |                                 |                          |
|                | <b>WH9</b>   | 9    |         |                                 |                          |
|                | <b>WH10</b>  | 10   |         |                                 |                          |

## CHARACTERISTICS

- Glove of newest generation
- Hand specific
- Tacky with micro-texture throughout the glove
- Without accelerator - reduced allergy risk
- Without plasticizers, phthalates, silicone oil and amide
- No sulphur added during compounding process
- Cleanroom produced and packed
- 40 % recycled materials for inner bag, outer bag, intermediate bag and carton liner
- 90 % recycled materials for carton box

## PERFORMANCE PARAMETER

|           |                               | SPECIFICATION | UNIT               |
|-----------|-------------------------------|---------------|--------------------|
| Fluoride  | F <sup>-</sup>                | < 0.010       | µg/cm <sup>2</sup> |
| Chloride  | Cl <sup>-</sup>               | < 0.300       | µg/cm <sup>2</sup> |
| Nitrite   | NO <sub>2</sub> <sup>-</sup>  | < 0.010       | µg/cm <sup>2</sup> |
| Bromide   | Br <sup>-</sup>               | < 0.010       | µg/cm <sup>2</sup> |
| Nitrate   | NO <sub>3</sub> <sup>-</sup>  | < 0.200       | µg/cm <sup>2</sup> |
| Phosphate | PO <sub>4</sub> <sup>3-</sup> | < 0.010       | µg/cm <sup>2</sup> |
| Sulphate  | SO <sub>4</sub> <sup>2-</sup> | < 0.050       | µg/cm <sup>2</sup> |
| Sodium    | Na <sup>+</sup>               | < 0.050       | µg/cm <sup>2</sup> |
| Calcium   | Ca <sup>2+</sup>              | < 0.300       | µg/cm <sup>2</sup> |
| Magnesium | Mg <sup>2+</sup>              | < 0.010       | µg/cm <sup>2</sup> |
| Potassium | K <sup>+</sup>                | < 0.050       | µg/cm <sup>2</sup> |
| Zinc      | Zn <sup>2+</sup>              | < 0.080       | µg/cm <sup>2</sup> |
| Ammonium  | NH <sub>4</sub> <sup>+</sup>  | < 0.050       | µg/cm <sup>2</sup> |



## PHYSICAL AND CHEMICAL PROPERTIES

|                                  | SPECIFICATION | UNIT                   |
|----------------------------------|---------------|------------------------|
| Force at Break (after aging)     | ≥ 6           | N                      |
| Tensile strength                 | ≥ 14          | MPa                    |
| Elongation                       | ≥ 400         | %                      |
| LPC (> 0.5 µm)                   | < 1,000       | Counts/cm <sup>2</sup> |
| NVR (DI water)                   | < 3.00        | µg/cm <sup>2</sup>     |
| Silicone oil, amide and DOP-FTIR | Not detected  | -                      |
| Endotoxin                        | < 10          | Units/gloves           |

## ADDITIONAL IMPORTANT PRODUCT INFORMATION

According to the EN 21420:2020 test, it is confirmed that during the production of CELOS gloves 1130310, 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, dibutylthiourea
- Formaldehyde
- Bisphenol A
- Bezoisothiazoline
- Cethylpyridinium Chloride
- Triphenyl phosphite, triphenyl phosphate, tricresyl phosphate
- Abietic acid derivatives
- Nickel

| PARAMETER               | TEST METHOD                                                 | RESULT          |
|-------------------------|-------------------------------------------------------------|-----------------|
| Chemotherapy Test       | EN455 Part 1:2020<br>EN455 Part 2:2015<br>EN455 Part 3:2015 | Pass            |
| Water-Leak-Test         | EN ISO 374-2:2019                                           | Pass            |
| Permeation              | ASTM D6978-05(2019)                                         | See table below |
| Degradation             | EN ISO 374-4:2019<br>EN ISO 374-1:2016+A1:2018              | See table below |
| Microbiological Testing | ISO 10993-5                                                 | See table below |
| Gamma Irradiation       | ISO 13485                                                   | See table below |



## PERFORMANCE PARAMETER

### 1. Permeation

| TEST CHEMICALS           | CODE | SAMPLE 1           | SAMPLE 2           | SAMPLE 3           |
|--------------------------|------|--------------------|--------------------|--------------------|
|                          |      | Breakthrough [min] | Breakthrough [min] | Breakthrough [min] |
| Isopropanol (70 %)       | -/-  | 123                | 143                | 129                |
| Hydrogen peroxide (30 %) | P    | 46 - 60            | 31 - 45            | 31 - 45            |
| Formaldehyde (37 %)      | T    | > 480              | > 480              | > 480              |
| Sodium hydroxide (40 %)  | K    | > 480              | > 480              | > 480              |

### 2. Degradation

| TEST CHEMICALS           | CODE | DEGRADATION | STANDARD DEVIATION |
|--------------------------|------|-------------|--------------------|
|                          |      | [%]         | [%]                |
| Isopropanol (70 %)       | -/-  | 81.8        | 3.2                |
| n-Heptane                | J    | 62.7        | 4.6                |
| Hydrogen peroxide (30 %) | P    | 39.8        | 11.3               |
| Formaldehyde (37 %)      | T    | 28.2        | 9.4                |
| Sodium hydroxide (40 %)  | K    | -3.7        | 13.7               |

### 3. Permeation Chemotherapy

| TEST CHEMICALS      | AMOUNT                | BREAKTHROUGH (MINIMUM)   | AVERAGE STEADY STATE PERM. |
|---------------------|-----------------------|--------------------------|----------------------------|
|                     |                       | Direction Time [minutes] | Rate [µg/cm2/minute]       |
| Carmustine          | 3.3 mg/ml (3,300 ppm) | 108.5                    | 0.11                       |
| Cisplatin           | 1 mg/ml (1,000 ppm)   | > 240                    | N/A                        |
| Cyclophosphamide    | 20 mg/ml (20,000 ppm) | > 240                    | N/A                        |
| Decarbazine         | 10 mg/ml (10,000 ppm) | > 240                    | N/A                        |
| Doxorubicin HCl     | 2 mg/ml (2,000 ppm)   | > 240                    | N/A                        |
| Etoposide           | 20 mg/ml (20,000 ppm) | > 240                    | N/A                        |
| Fluorouracil        | 50 mg/ml (50,000 ppm) | > 240                    | N/A                        |
| Ifosfamide          | 50 mg/ml (50,00 ppm)  | > 240                    | N/A                        |
| Mitoxantrone        | 1 mg/ml (1,000 ppm)   | > 240                    | N/A                        |
| Paclitaxel          | 6 mg/ml (6,000 ppm)   | > 240                    | N/A                        |
| Thiotepa            | 10 mg/ml (10,000 ppm) | 26.6                     | 0.02                       |
| Vincristine Sulfate | 1 mg/ml (1,000 ppm)   | > 240                    | N/A                        |

#### 4. Microbiological Testing

| SAMPLE IDENTIFICATION                              | REP | SAMPLE WEIGHT | SAMPLE AREA     | EXTRACT VOLUME | PERCENT LYSIS | GRAD/ REACTIVITY |
|----------------------------------------------------|-----|---------------|-----------------|----------------|---------------|------------------|
|                                                    |     |               | cm <sup>2</sup> |                | %             |                  |
| Culture Media Blank                                | 1   | N/A           | N/A             | N/A            | 0.56          | 0, None          |
|                                                    | 2   | N/A           | N/A             | N/A            | 0.23          | 0, None          |
|                                                    | 3   | N/A           | N/A             | N/A            | -0.79         | 0, None          |
| Positive Control, Polyisoprene Glove               | 1   | 0.97          | 107             | 17             | 95            | 4, Severe        |
|                                                    | 2   | 0.99          | 107             | 17             | 92            | 4, Severe        |
|                                                    | 3   | 1.00          | 107             | 17             | 94            | 4, Severe        |
| Negative Control, High Density Polyethylene (HDPE) | 1   | 1.92          | 20              | 9.5            | 24            | 2, Mild          |
|                                                    | 2   | 1.90          | 20              | 9.5            | 20            | 2, Mild          |
|                                                    | 3   | 1.94          | 20              | 9.5            | 21            | 2, Mild          |
| 13" Cleanroom Nitrile Gloves                       | 1   | 0.46          | 88.4            | 14.7           | 32            | 2, Mild          |
|                                                    | 2   | 0.47          | 88.4            | 14.7           | 32            | 2, Mild          |
|                                                    | 3   | 0.49          | 88.4            | 14.7           | 39            | 2, Mild          |

The test article elicited a Grade 2 (Not more than 50 % of the cells lysed; not more than 50 % growth inhibition observable) response and therefore does meet the ISO 10993-5 Biocompatibility test requirements.

#### 5. Gamma Irradiation

|                | MINIMUM | MAXIMUM |
|----------------|---------|---------|
| Specified Dose | 25 kGy  | 50 kGy  |





## FOOD SUITABILITY

This data sheet shall give an overview of results for food contact testing of Cleanroom Nitrile CELOS® Glove 2.20. The results below reflect migration testing in accordance 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 10955:2024                                                                                        | Pass            |
| Smell transfer                                  |                                                                                                       | Pass            |
| Transfer of taste                               |                                                                                                       | Pass            |
| Overall migration                               | DIN EN 1186 ff.:2002                                                                                  | See table below |
| Overall migration, MPPO                         | DIN EN 1186-13:2002                                                                                   | See table below |
| Acrylonitrile, 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 HPLC-MS/MS<br>– quantification by MS-0036943:2020                                     | Pass            |
| Color migration of pigmented plastics           | BGESUNDHBL 15 (1972): 285                                                                             | See table below |
| Metals, total content at decomposition          | ICP-OES according to DIN EN ISO 11885;<br>In-house method – quantification by<br>MS-0022823:2023      | See table below |
| Migration of heavy metals, rubber               | ISP-MS according to DIN EN IS 17294-2:2023;<br>In-house method - quantification by<br>MS-0022823:2023 | See table below |
| N-nitrosamines and<br>N-nitrosatable substances | DIN EN 12868:2017                                                                                     | Pass            |
| Polycyclic aromatic hydrocarbons (PAH)          | AfPS GS 2019:01 PAK:2019                                                                              | Pass            |

## 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 and article 4 of Consumer Goods Ordinance 817.023.21 (CH).

## Overall migration

|                 | OVERALL MIGRATION       | PASS / FAIL |
|-----------------|-------------------------|-------------|
|                 | [mg / dm <sup>2</sup> ] |             |
| Acetic Acid 3 % | 5.1                     | Pass        |
| Ethanol 50 %    | 9.3                     | Pass        |

The samples comply with the limit value for products in contact with food according to the Commission Directives 2006/141/EC and 2006/125/EC.

## Overall migration, MPPO

|      | OVERALL MIGRATION       | PASS / FAIL |
|------|-------------------------|-------------|
|      | [mg / dm <sup>2</sup> ] |             |
| MPPO | 3.9                     | Pass        |

The samples comply with the limit value for products in contact with food according to the Commission Directives 2006/141/EG and 2006/125/EG.

## Migration of Acrylonitrile and 1,3 – Butadiene

|                    | ACRYLONITRILE  |                 | 1,3 – BUTADIENE |                 |
|--------------------|----------------|-----------------|-----------------|-----------------|
| Migration Solution | Oil            | Acetic Acid 3 % | Oil             | Acetic Acid 3 % |
| Results (mg / kg)  | Not detectable | Not detectable  | Not detectable  | Not detectable  |
| Pass / Fail        | Pass           | Pass            | Pass            | Pass            |

The samples comply with limit value for products in contact with foodstuffs according to the Regulation (EU) No 10/2011 and Consumer Goods Ordinance 817.023.21 (CH).



### Formaldehyde content

|              | RESULT | PASS / FAIL |
|--------------|--------|-------------|
|              | [mg/l] |             |
| 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“.

### Color migration of pigmented plastics

|                | CONTACT MEDIUM  | PASS / FAIL |
|----------------|-----------------|-------------|
| Color fastness | Water           | Pass        |
| Color fastness | Acetic acid 3 % | Pass        |
| Color fastness | Ethanol 50 %    | Pass        |
| Color fastness | Coconut oil     | Pass        |

The samples comply with the recommendation of the BfR part IX „Colourants for colouring plastics and other polymers for consumer goods“, „synthetic materials in food transport“ respectively Resolution AP (89) 1 on the use of colourants in plastic materials coming into contact with food, no traces of colour may migrate into the food simulant.

### Metals, total content at decomposition

|         | RESULT   | PASS / FAIL |
|---------|----------|-------------|
|         | [%]      |             |
| Lead    | < 0.0005 | Pass        |
| Cadmium | < 0.0005 | Pass        |

The samples comply according to the Regulation (EC) No 1907/2006 (REACH). Duty to communicate on SVHC, if the concentration of elementary lead or cadmium in the article is higher than 0.1% (m/m).



## Migration of metals, rubber

|           | RESULT                   | MIGRATION SOLUTION | PASS / FAIL | REQUIREMENT                                                                                 |
|-----------|--------------------------|--------------------|-------------|---------------------------------------------------------------------------------------------|
|           | [mg/kg]<br>food simulant |                    |             | [C = Category]                                                                              |
| Aluminium | 0.011                    | Acetic acid 3 %    | Pass        | Aluminium content:<br><b>C 1/2/3*</b> :<br>max. 1 mg/kg food or food simulant               |
| Lead      | < 0.01                   | Acetic acid 3 %    | Pass        | Lead impurities:<br><b>C 1/2/3*</b> not detectable<br>(< 0.001 mg/kg food or food simulant) |
| Zinc      | 7.2                      | Acetic acid 3 %    | Pass        | Zinc content:<br><b>C 1/2/3*</b> :<br>25 mg/kg food or food simulant                        |

### \*C1 [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).

### \*C2 [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.

### \*C3 [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“.

