





**manual<sup>®</sup>**
**UA 120**

# ULTRANITRILE

**PRODUCT INFORMATION**

|                     |   |
|---------------------|---|
| Type:               | Latex-free, powder-free and non-sterile examination glove                   |
| Primary Material:   | Nitrile (Acrylonitrile-butadiene)   |
| Design and Feature: | Ambidextrous, straight fingers, textured fingertips, beaded cuff            |
| Colour:             | Blue  |
| Powder:             | ≤ 2 mg/glove (powder-free), no powder lubricant added                       |
| Packing:            | 200 gloves by weight per box (XL: 180 gloves), 10 boxes per shipping carton |
| Shelf Life          | 5 years upon date of manufacture  |

## Dimensions:

| Gloves Size | Reorder # | Palm Width (mm) | Min. Length (mm) |
|-------------|-----------|-----------------|------------------|
| Extra-small | UN120-00  | 75 ± 5          | 240              |
| Small       | UN120-01  | 85 ± 5          | 240              |
| Medium      | UN120-02  | 95 ± 5          | 240              |
| Large       | UN120-03  | 106 ± 5         | 240              |
| Extra-large | UN120-04  | 115 ± 5         | 240              |

## Thickness:

| Location of Thickness Measurement | Single Wall (mm) |
|-----------------------------------|------------------|
| Palm (at center of palm)          | Min 0.06         |

## Physical Properties:

| Parameters         | Before Aging | After Aging |
|--------------------|--------------|-------------|
| Force At Break (N) | Min 6.0      | Min 6.0     |

## Pre-Shipment Inspection:

| Inspection Criteria                 | Inspection Level | AQL |
|-------------------------------------|------------------|-----|
| Dimension                           | S-2              | 4.0 |
| Physical Properties                 | S-2              | 4.0 |
| 1000ml Water Leak Test              | G-1              | 1.5 |
| Visual Inspection for Major Defects | S-4              | 2.5 |
| Visual Inspection for Minor Defects | S-4              | 4.0 |

## Product Conformance:

Certified as Personal Protective Equipment of Complex Design Category III as per PPE Regulation (EU) 2016/425, type tested in accordance with EN ISO 374-1:2016, EN ISO 374-5:2016 and EN 420:2003+A1:2009. Medical Device of Class I as per MDR (EU) 2017/745, tested in accordance with EN 455 parts 1-4.





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## Konformitätserklärung – Declaration of Conformity

### Produktspezifikation / Product Details:

Produktbezeichnung / Product Name

**manual UN120 Ultra Nitrile Examination Gloves**

Größe/Size – Bestellnummer/reordernumber

|             |   |          |
|-------------|---|----------|
| Extra Small | – | UN120-00 |
| Small       | – | UN120-01 |
| Medium      | – | UN120-02 |
| Large       | – | UN120-03 |
| Extra Large | – | UN120-04 |

Klassifizierung nach RL 93/42/EWG, Anhang IX / Klasse I nach Regel 5  
Classification according to 93/42/EEC, annex IX / Class I per rule 5

Wir erklären in alleiniger Verantwortung, dass die oben beschriebenen Produkte den grundlegenden Anforderungen gemäß Anhang I der Richtlinie 93/42/EWG des Rates gemäß der Änderung nach 2007/47/EC entsprechen. Die Produkte werden mit dem CE-Kennzeichen versehen und erfüllen die Anforderungen der einzelstaatlich umgesetzten Normen EN 455-1:2000, EN 455-2:2009+A2:2013, EN 455-3:2006 und EN 455-4:2009.

Diese Produkte entsprechen den Anforderungen der Verordnung (EU) 2016/425 des Rates und, wo dies zutreffend ist, auch den einzelstaatlich umgesetzten Normen EN 420:2003+A1:2009, EN 374-1:2016 und EN ISO 374-5:2016, und unterliegen dem Bewertungsverfahren gemäß Modul D der Verordnung (EU) 2016/425.

We declare under sole responsibility that the products described above meet the essential requirements set out in Annex I of Council Directive 93/42/EEC amended by 2007/47/EC which apply to them. The products are CE marked and in conformity with the national transposed harmonized standards EN 455-1:2000, EN 455-2:2009+A2:2013, EN 455-3:2006 and EN 455-4:2009.

These products are in conformity with the provisions of Regulation (EU) 2016/425 and, where such is the case, with the national standard transposing harmonized standard no. EN 420:2003+A1:2009, EN ISO 374-1:2016 and EN 374-5:2016 and are subject to the procedure set out in Module D of Regulation (EU) 2016/425.

Ort, Datum / Place and date of issue: Vienna, April 19<sup>th</sup>, 2019

Franz Reisinger  
(Managing Director, Heliomed Handelsg.m.b.H)

## ANNEX

### EU TYPE EXAMINATION CERTIFICATE Nr. 043/2020/0553

#### 1. Applicant

Heliomed Handelsges.m.b.H  
An den Langen Lussen 8/4  
A-1190 Vienna  
Austria

#### 2. Description

EN ISO 374-1 / Type B



J K T

EN ISO 374-5



VIRUS

#### 3. Materials and accessories

##### Gloves

- manual® Ultra Nitrile Gloves Blue UN120-xx



#### 4. Technical documentation

##### Summary test results

EN 420:2003+A1:2009

Gloves

**manual® Ultra Nitrile Gloves Blue UN120-xx**

| Method           | Description                 | Result | Class |
|------------------|-----------------------------|--------|-------|
| EN 1413          | pH - textile                | PASS   |       |
| EN 14362-1       | AZO dyes for colored gloves | /      | /     |
| EN 420 length    | Length                      | PASS   |       |
| EN 420 dexterity | Dexterity                   | /      | /     |

EN ISO 374-1:2016

Gloves

**manual® Ultra Nitrile Gloves Blue UN120-xx**

| Method        | Description   | Result | Class   |
|---------------|---------------|--------|---------|
| EN 374-2      | Penetration   | PASS   |         |
| EN 16523-1    | Permeation J  | PASS   | Level 3 |
| EN 16523-1    | Permeation K  | PASS   | Level 6 |
| EN 16523-1    | Permeation T  | PASS   | Level 6 |
| EN 374-4      | Degradation J | PASS   |         |
| EN 374-4      | Degradation K | PASS   |         |
| EN 374-4      | Degradation T | PASS   |         |
| Type of glove |               | PASS   | Type B  |

EN ISO 374-5:2016

Gloves

**manual® Ultra Nitrile Gloves Blue UN120-xx**

| Method            | Description                | Result | Class |
|-------------------|----------------------------|--------|-------|
| EN 374-2          | Penetration                | PASS   |       |
| ISO 16604 Proc. B | Protection against viruses | PASS   |       |

## Description/Picture of article

Article **manual® Ultra Nitrile Gloves Blue**  
**UN120-00 · UN120-01 · UN120-02 · UN120-03 · UN120-04**



The above picture is a general picture of the article. Possible variations of the above article can be present in the technical file.

**Note :**

Any modification in material, design, or other technical features must be brought to the attention of the Notified Body.