

## Technical Construction File

File No.: MDD-AC-2019011001

<b>Type of Equipment:</b>	<b>Disposable Vinyl Gloves</b>
<b>Model No.:</b>	<b>XS, S, M, L, XL, XXL</b>
<b>Issued Date:</b>	<b>2019/1/10</b>
<b>Brand Name/Trade mark:</b>	<b>/</b>
<b>Directive(s)</b>	<b>93/42/EEC Medical devices</b>
<b>Standard(s)</b>	<b>EN 455-1:2000, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009</b>



Presented by

**Anhui ANCHO Rubber & Plastic Technology Co., Ltd****Buyun road, Xiaoxian Economic Development Zone, Suzhou City,****Anhui Province**

# **Content**

## **Part I: General**

- 1.1 General description of product
- 1.2 Variations of the series products
- 1.3 List of applicable regulations and standards
- 1.4 Quality control system

## **Part II: Assessment report**

- 2.1 EN 455-1:2000 & EN 455-2:2015 & EN 455-3:2015 &EN 455-4:2009  
Assessment report

## **Annex: Technical Information**

- Annex 1 Photos

## ***Part I : General***

### ***1.1 General description of product***

This product is made of polyvinyl chloride. It has sufficient strength and barrier performance. Non-sterile, disposable. It is mainly suitable for wearing on the hands of doctors to check or touch the patient's condition.

### ***1.2 Variations of the series products***

Regarding the whole family of the series, they can be divided into various different groups according to their main features, they are:

#### **XS, S, M, L, XL, XXL**

All models are with the same product structure but with some small differences as described as the following:

1. The size is different.
2. The color is different.

To present the conformity of this series products with Medical devices, we discuss the conformity systematically with the relative Directive and standards for XS as a basic evaluation in clause.

### ***1.3 List of applicable regulations and standards***

#### Regulations

- Medical devices: 93/42/EEC

#### Standards

- EN 455-1:2000

Medical gloves for single use - Part 1: Requirements and testing for freedom from holes

- EN 455-2:2015

Medical gloves for single use - Part 2: Requirements and testing for physical properties

- EN 455-3:2015

Medical gloves for single use - Part 3: Requirements and testing for biological evaluation

- EN 455-4:2009

Medical gloves for single use - Part 4: Requirements and testing for shelf life determination

### ***1.4 Quality control system***

In order to ensure the conformity of the series production, the ANHUI ANCHO RUBBER & PLASTIC TECHNOLOGY CO., LTD. has taken the related procedures mentioned below:

(1) Apply for the consultant from the qualified body.

The ANHUI ANCHO RUBBER & PLASTIC TECHNOLOGY CO., LTD. has applied for the consultant from Technical Inspection Certification. The complete technical construction file (TCF) have been established before applying for the CE marking certificate.

(2) Carry out the inspection for parts and components according to the TCF.

Before the assemblies of the series production, the QC engineers of ANCHO has to check and inspect the technical specifications and intended functions of parts and components to ensure the correct use of them according to the contents of TCF and principle described in the related technical information.

(3) Carry out the inspection & testing for the products before packing.

Before packing the products, the QC engineers of ANCHO have to do the necessary inspection and testing to ensure the conformity of related requirements. In particular, they should do the testing and inspection of electrical characteristics and outer feature.

(4) Carry out the inspection for the package.

After finishing the necessary inspection and testing for the products, an inspection for the packing has to be done to ensure the necessary elements being included in this packing before shipment.

(5) Provision for the change of design.

Any change of the products described in this TCF must be checked in detail and written down again in the TCF by the designer of ANCHO if the change may effects the related electrical or mechanical characteristics.

(6) Provision for the Quality Assurance.

For the provisions of internal control measures to ensure the conformity of series production of the machines, ANHUI ANCHO RUBBER & PLASTIC TECHNOLOGY CO., LTD. has built an internal quality control system in accordance with the international standard of ISO 9001.

**Part II: Assessment report**

2.1 EN 455-1:2000 & EN 455-2:2015 & EN 455-3:2015 &EN 455-4:2009

Assessment report

<p><b>ASSESSMENT REPORT</b></p> <p><b>per</b></p> <p><b>EN 455-1:2000 &amp; EN 455-2:2015 &amp; EN 455-3:2015 &amp; EN 455-4:2009</b></p>
<p>TCF</p> <p>Reference No. ....: MDD-AC-2019011001</p> <p>Tested by(+ signature).....: Lisa Wu</p> <p>Reviewed by(+ signature).....: Smith Fang</p> <p>Date of issue .....: 2019-01-10</p> <p>Number of pages (Report) .....: 19</p>
<p>Client</p> <p>Name .....: Anhui ANCHO Rubber &amp; Plastic Technology Co., Ltd</p> <p>Address .....: Buyun road, Xiaoxian Economic Development Zone, Suzhou City, Anhui Province</p>
<p>Test specification</p> <p>Standard .....: EN 455-1:2000 &amp; EN 455-2:2015 &amp; EN 455-3:2015 &amp; EN 455-4:2009</p> <p>Test procedure .....: CE-MDD</p> <p>Non-standard test method .....: N.A.</p>
<p>Test item description :</p> <p>Manufacturer.....: Anhui ANCHO Rubber &amp; Plastic Technology Co., Ltd</p> <p>Product Name.....: Disposable Vinyl Gloves</p> <p>Model/Type reference.....: XS</p> <p>Rating(s) .....: N.A.</p>
<p><b>General product information:</b></p> <p>This product is made of polyvinyl chloride. It has sufficient strength and barrier performance. Non-sterile, disposable. It is mainly suitable for wearing on the hands of doctors to check or touch the patient's condition.</p>

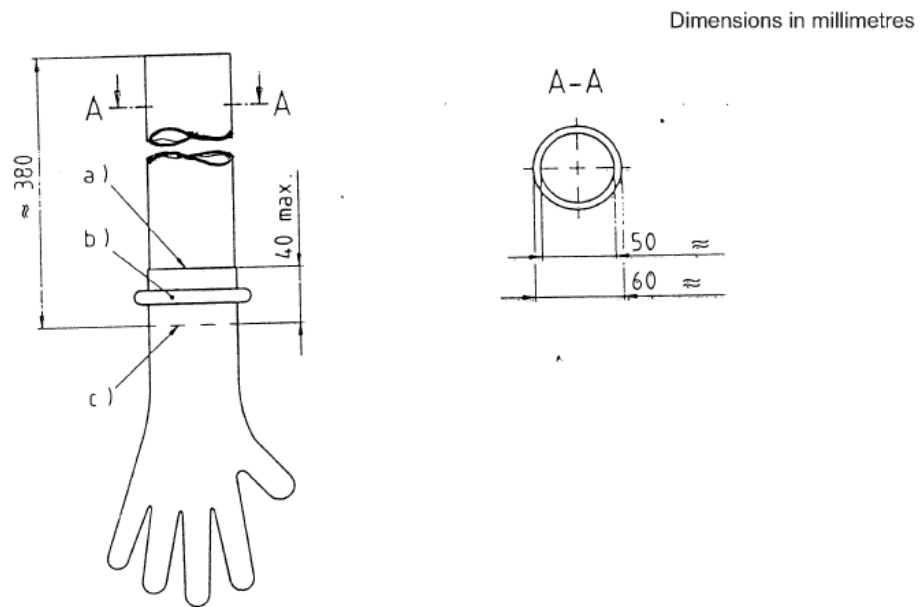
<b>EN 455-1:2000</b>			
<b>Clause</b>	<b>Requirement Test</b>	<b>Result-Remark</b>	<b>Verdict</b>
<b>1</b>	<b>Scope</b>		<b>N</b>
	This part of this standard specifies requirements and gives the test method for medical gloves for single use in order to determine freedom from holes.		<b>N</b>
<b>2</b>	<b>Normative Reference</b>		<b>N</b>
	This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).		<b>N</b>
<b>3</b>	<b>Term and definition</b>		<b>-</b>
	For the purposes of this standard the following term and definition apply:		<b>-</b>
<b>3.1</b>	<b>medical gloves for single use</b>		<b>P</b>
	gloves intended for use in the medical field to protect patient and user from cross-contamination		<b>P</b>
<b>4</b>	<b>Requirement</b>		<b>P</b>
	Medical gloves for single use shall not leak when tested in accordance with clause 5.		<b>P</b>
<b>5</b>	<b>Watertightness test for detection of holes</b>		<b>P</b>
<b>5.1</b>	<b>Referee testing</b>		<b>P</b>
	Vertically position a filling tube of dimensions shown in Figure 1 or of dimensions to fit the glove and such that the tube is capable of holding any of the 1 000 ml of water that may exceed the natural fill volume of the glove.		<b>P</b>
	Attach the glove to the filling tube, overlapping the cuff by a maximum of 40 mm over the end of the tube and secure it by suitable means to obtain a watertight seal without damaging the glove (see Figure 1).	See Figure 1.	<b>P</b>
	Add 1 000 ml $\pm$ 50 ml of water at a temperature of (15 to 35) °C into the open end of the filling tube, allowing the water to pass freely into the glove.		<b>P</b>
	Immediately inspect the glove visually for water		<b>P</b>

<b>EN 455-1:2000</b>			
<b>Clause</b>	<b>Requirement Test</b>	<b>Result-Remark</b>	<b>Verdict</b>
	leakage. Allow the glove to hang and visually inspect the glove for water leakage again after a period of 2 min to 3 min.		<b>P</b>
	If, because of distension of the glove, the water does not rise to within 40 mm of the cuff end, raise the glove after the second inspection by a suitable means until the water level reaches 40 mm from the cuff end. Inspect visually the previously untested portion of the glove after a further period of 2 min to 3 min.		<b>P</b>
	Disregard leakages within 40 mm of the cuff.		<b>P</b>
<b>5.2</b>	<b>Routine testing</b>		<b>P</b>
	Routine testing shall be either by the watertightness test given in 5.1 or by another test which is validated against this test.		<b>P</b>
<b>6</b>	<b>Sampling, inspection level and AQL</b>		<b>N</b>
	Each lot shall be sampled in accordance with ISO 2859-1 general inspection level 1, but utilizing a minimum sample size and corresponding acceptance/rejection numbers equivalent to sample size code letter L. When tested by the method described in 5.1 for referee purpose, the compliance level for freedom from holes shall be an AQL of 1,5.		<b>N</b>
<b>7</b>	<b>Test report</b>		<b>P</b>
	Any test report shall include at least the following information:		<b>P</b>
	-a reference to this part of EN 455		<b>P</b>
	-the type of gloves and manufacturing batch code;		<b>P</b>
	-the name and address of the manufacturer or distributor and test laboratory, if different;		<b>P</b>
	-the date of the test performed;		<b>P</b>
	-the test results (batch size, sample size, number of non-conforming gloves).		<b>P</b>



**EN 455-1:2000**

Clause	Requirement Test	Result-Remark	Verdict
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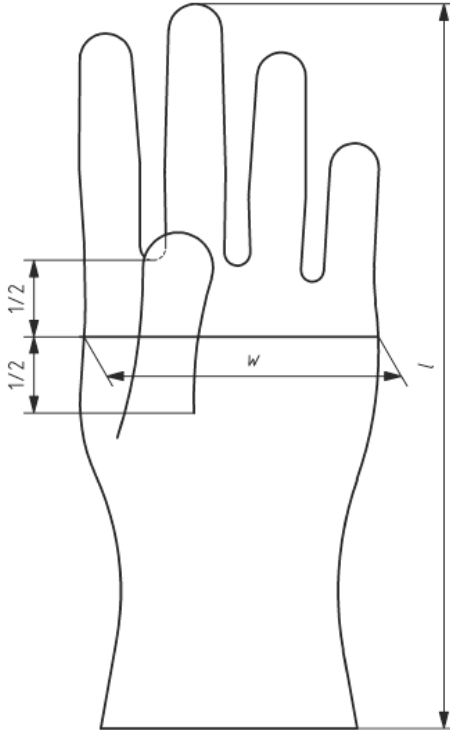


**Key**

- a) Cuff end of glove
- b) Locking device
- c) Fill tube overlapping

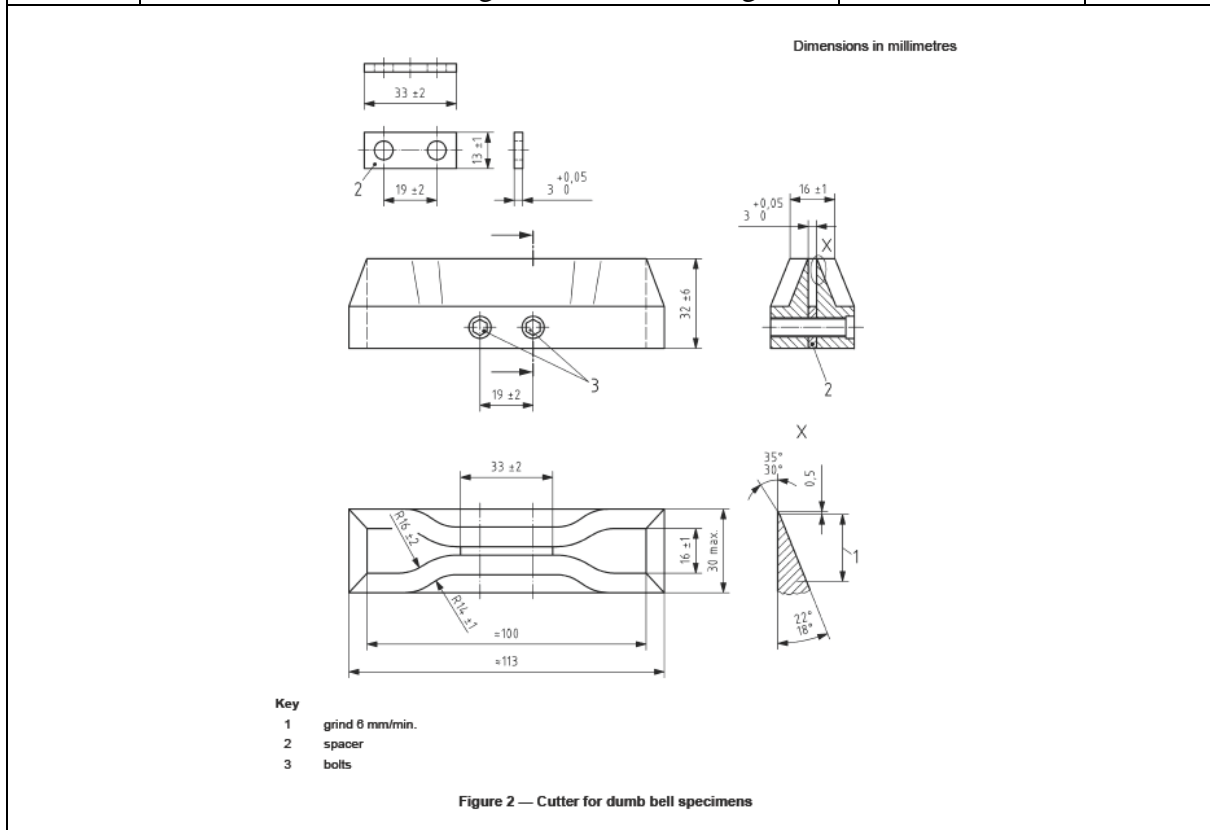
**Figure 1 - Watertightness test - Filling tube**

<b>EN 455-2:2015</b>			
<b>Clause</b>	<b>Requirement Test</b>	<b>Result-Remark</b>	<b>Verdict</b>
<b>1</b>	<b>Scope</b>		<b>P</b>
	This European Standard specifies requirements and gives test methods for physical properties of single-use medical gloves (i.e. surgical gloves and examination/procedure gloves) in order to ensure that they provide and maintain in use an adequate level of protection from cross contamination for both patient and user.		<b>P</b>
	This European Standard does not specify the size of a lot. Attention is drawn to the difficulties that can be associated with the distribution and control of very large lots. The recommended maximum individual lot size for production is 500 000.		<b>P</b>
<b>2</b>	<b>Normative references</b>		<b>N</b>
	The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.		<b>N</b>
<b>3</b>	<b>Terms and definitions</b>		<b>-</b>
	For the purposes of this document, the following terms and definitions apply.		<b>-</b>
<b>3.1</b>	<b>medical gloves for single use</b>		<b>P</b>
	gloves intended for use in the medical field to protect patient and user from cross-contamination		<b>P</b>
<b>3.2</b>	<b>surgical gloves</b>		<b>P</b>
	sterile, anatomically shaped medical gloves with the thumb positioned towards the palmar surface of the index finger rather than lying flat, and intended for use in invasive surgery		<b>P</b>
<b>3.3</b>	<b>examination gloves procedure gloves</b>		<b>P</b>
	sterile or non-sterile medical gloves, which may or may not be anatomically shaped, intended for conducting medical examinations, diagnostic and therapeutic procedures and for handling contaminated medical material		<b>P</b>
<b>3.4</b>	<b>lot</b>		<b>N</b>
	collection of gloves of the same design, colour, shape, size and formulation, manufactured at		<b>N</b>

<b>EN 455-2:2015</b>			
<b>Clause</b>	<b>Requirement Test</b>	<b>Result-Remark</b>	<b>Verdict</b>
	essentially the same time, using the same process, raw materials of the same specifications, common equipment and packed in the same type of individual container		<b>N</b>
<b>4</b>	<b>Dimensions</b>		<b>P</b>
<b>4.1</b>	<b>General</b>		<b>P</b>
	When measured as described in 4.2 and 4.3 taking 13 samples from each lot, the median value obtained for the dimensions shall be as given in Tables 1 and 2.	See Tables 1. See Tables 2.	<b>P</b>
 <p><b>Key</b>  <i>w</i> width  <i>l</i> length</p> <p style="text-align: center;"><b>Figure 1 — Designation of length and width of gloves</b></p>			
<b>4.2</b>	<b>Length</b>		<b>P</b>
	Measure the length (dimension <i>l</i> , as designated in Figure 1) by freely suspending the glove with the middle finger on a vertical graduated rule having a rounded tip so as to fit the shape of the finger tip of the glove. Remove wrinkles and folds without stretching the glove. Record the median measured length.	See Figure 1.	<b>P</b>

<b>EN 455-2:2015</b>																																				
<b>Clause</b>	<b>Requirement Test</b>	<b>Result-Remark</b>	<b>Verdict</b>																																	
	For greater ease of measurement, the ruler may be angled backwards slightly so that the glove is in contact with the ruler.		<b>P</b>																																	
<b>4.3</b>	<b>Width</b>		<b>P</b>																																	
	Measure the width (dimension <i>w</i> , as designated in Figure 1), to the nearest mm, using a ruler, with the glove placed on a flat surface. Do not stretch the glove.	See Figure 1.	<b>P</b>																																	
<b>Table 1 — Dimensions of surgical gloves</b>																																				
<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: center;">Size</th> <th style="text-align: center;">Median length<sup>a</sup> <i>l</i> in mm</th> <th style="text-align: center;">Median width<sup>b c</sup> <i>w</i> in mm</th> </tr> </thead> <tbody> <tr><td style="text-align: center;">5</td><td style="text-align: center;">≥ 250</td><td style="text-align: center;">67 ± 4</td></tr> <tr><td style="text-align: center;">5,5</td><td style="text-align: center;">≥ 250</td><td style="text-align: center;">72 ± 4</td></tr> <tr><td style="text-align: center;">6</td><td style="text-align: center;">≥ 260</td><td style="text-align: center;">77 ± 5</td></tr> <tr><td style="text-align: center;">6,5</td><td style="text-align: center;">≥ 260</td><td style="text-align: center;">83 ± 5</td></tr> <tr><td style="text-align: center;">7</td><td style="text-align: center;">≥ 270</td><td style="text-align: center;">89 ± 5</td></tr> <tr><td style="text-align: center;">7,5</td><td style="text-align: center;">≥ 270</td><td style="text-align: center;">95 ± 5</td></tr> <tr><td style="text-align: center;">8</td><td style="text-align: center;">≥ 270</td><td style="text-align: center;">102 ± 6</td></tr> <tr><td style="text-align: center;">8,5</td><td style="text-align: center;">≥ 280</td><td style="text-align: center;">108 ± 6</td></tr> <tr><td style="text-align: center;">9</td><td style="text-align: center;">≥ 280</td><td style="text-align: center;">114 ± 6</td></tr> <tr><td style="text-align: center;">9,5</td><td style="text-align: center;">≥ 280</td><td style="text-align: center;">121 ± 6</td></tr> </tbody> </table> <p><sup>a</sup> Dimension <i>l</i> as designated in Figure 1.  <sup>b</sup> Dimension <i>w</i> as designated in Figure 1.  <sup>c</sup> The width requirements are for gloves made from natural rubber latex and all other elastomeric materials. These dimensions may not be appropriate for gloves made from other materials.</p>				Size	Median length <sup>a</sup> <i>l</i> in mm	Median width <sup>b c</sup> <i>w</i> in mm	5	≥ 250	67 ± 4	5,5	≥ 250	72 ± 4	6	≥ 260	77 ± 5	6,5	≥ 260	83 ± 5	7	≥ 270	89 ± 5	7,5	≥ 270	95 ± 5	8	≥ 270	102 ± 6	8,5	≥ 280	108 ± 6	9	≥ 280	114 ± 6	9,5	≥ 280	121 ± 6
Size	Median length <sup>a</sup> <i>l</i> in mm	Median width <sup>b c</sup> <i>w</i> in mm																																		
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<b>Table 2 — Dimensions of examination/procedure gloves</b>																																				
<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: center;">Size</th> <th style="text-align: center;">Median length<sup>a</sup> <i>l</i> in mm</th> <th style="text-align: center;">Median width<sup>b c</sup> <i>w</i> in mm</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">Extra Small</td> <td rowspan="5" style="text-align: center;">≥ 240</td> <td style="text-align: center;">≤ 80</td> </tr> <tr> <td style="text-align: center;">Small</td> <td style="text-align: center;">80 ± 10</td> </tr> <tr> <td style="text-align: center;">Medium</td> <td style="text-align: center;">95 ± 10</td> </tr> <tr> <td style="text-align: center;">Large</td> <td style="text-align: center;">110 ± 10</td> </tr> <tr> <td style="text-align: center;">Extra Large</td> <td style="text-align: center;">≥ 110</td> </tr> </tbody> </table> <p>NOTE Manufacturers may optionally use the sizes and dimensions given in Table 1 in order to provide a wider range of glove sizes.  <sup>a</sup> Dimension <i>l</i> as designated in Figure 1.  <sup>b</sup> Dimension <i>w</i> as designated in Figure 1.  <sup>c</sup> The width requirements are for gloves made from natural rubber latex and all other elastomeric materials. These dimensions may not be appropriate for gloves made from other materials.</p>				Size	Median length <sup>a</sup> <i>l</i> in mm	Median width <sup>b c</sup> <i>w</i> in mm	Extra Small	≥ 240	≤ 80	Small	80 ± 10	Medium	95 ± 10	Large	110 ± 10	Extra Large	≥ 110																			
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Extra Large		≥ 110																																		
<b>5</b>	<b>Strength</b>		<b>P</b>																																	
<b>5.1</b>	<b>General</b>		<b>P</b>																																	

<b>EN 455-2:2015</b>			
<b>Clause</b>	<b>Requirement Test</b>	<b>Result-Remark</b>	<b>Verdict</b>
	Different glove materials require different force at break requirements to ensure an acceptable performance. Absolute force at break values do not directly correlate with the in use performance. Selection of appropriate glove materials for the intended application shall be part of the risk management process.		<b>P</b>
	When the strength of the glove is tested as described in 5.2 at a temperature of $(23 \pm 2) ^\circ\text{C}$ and a relative humidity of $(50 \pm 5) \% \text{ r.h.}$ the force at break of gloves shall be as given in Table 3.		<b>P</b>
<b>5.2</b>	<b>Force at break</b>		<b>P</b>
<b>5.2.1</b>	Ageing and shelf life requirements are described in EN 455-4:2009.		<b>P</b>
<b>5.2.2</b>	Obtain one dumb-bell test piece from each of 13 gloves taken from a single lot (from seven pairs of gloves where applicable) using a cutter as specified in Figure 2 from the palm, back of the hand or cuff areas of each glove in the test sample, avoiding textured areas if possible and taking the test pieces in the direction of the longitudinal axis of the glove.	See Figure 2.	<b>P</b>



<b>EN 455-2:2015</b>			
<b>Clause</b>	<b>Requirement Test</b>	<b>Result-Remark</b>	<b>Verdict</b>
<b>5.2.3</b>	Determine the force at break of the 13 test pieces after conditioning for a minimum of 16 h. The tensometer should be equipped with a load cell appropriate for the strength of the sample under test, with jaws that firmly grip but do not damage the test specimen and with a crosshead speed of 500 mm/min.		<b>P</b>
	If a test piece breaks at the shoulder, it is not necessary to repeat the test on another test piece.		<b>P</b>
<b>5.2.4</b>	a) Determine the single wall thickness (tf) of the same glove as in 5.2.2 at a point on the middle finger within $(13 \pm 3)$ mm of the fingertip by measuring the double wall thickness as described in method A of ISO 23529:2010, Clause 7.1, using a gauge with a foot pressure of $(22 \pm 5)$ kPa. Take the single wall thickness as one half of the measured double wall thickness.		<b>P</b>
	b) Measure the thickness of the dumb-bell test pieces (tx) as described in method A of ISO 23529:2010, Clause 7.1, using the gauge described in 5.2.4 a).		<b>P</b>
	c) Compare the values of tf and tx. If $tf/tx \geq 0,9$ , no correction to the measured force at break is necessary. If $tf/tx < 0,9$ , correct the measured value by multiplying the measured force at break (see 5.2.3) by a factor of $tf/tx$ .		<b>P</b>
	Although there is no requirement for thickness in this standard, it is recognised that the fingers of a glove may, because of design or manufacturing processes, be significantly thinner and therefore weaker in terms of force to break than at the points from which the test pieces were taken. It is important to ensure that the minimum force at break requirements given in Table 3 is maintained at the fingertips. If the difference in thickness between the fingertip and the point from which the test pieces were taken is small (less than 10 %), no correction is necessary. If this difference is greater than 10 %, a correction factor based on the relative thickness is applied to the measured force at break to obtain a true estimate of the strength of the glove at the	See Table 3.	<b>P</b>

<b>EN 455-2:2015</b>																					
<b>Clause</b>	<b>Requirement Test</b>	<b>Result-Remark</b>	<b>Verdict</b>																		
	fingertip.		<b>P</b>																		
5.2.5	Record the force at break, in N, for each of the 13 samples, corrected as described in 5.2.4 if necessary. The median of the recorded results shall comply with the values of Table 3.	See Table 3.	<b>P</b>																		
<b>Table 3 — Median values of force at break</b>																					
<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th rowspan="3" style="width: 35%;"></th> <th colspan="3" style="text-align: center;">Force at break in Newton</th> </tr> <tr> <th style="text-align: center;">Surgical gloves a)</th> <th colspan="2" style="text-align: center;">Examination/procedure gloves</th> </tr> <tr> <th style="text-align: center;">b)</th> <th style="text-align: center;">c)</th> <th style="text-align: center;"></th> </tr> </thead> <tbody> <tr> <td style="text-align: center;"><b>Throughout shelf life tested according to 5.2 and within 12 months of manufacture tested according to 5.3</b></td> <td style="text-align: center;">≥ 9,0</td> <td style="text-align: center;">≥ 6,0</td> <td style="text-align: center;">≥ 3,6</td> </tr> <tr> <td colspan="4">           a) Requirements for all surgical gloves.            b) Requirements for all examination gloves, except gloves made from thermoplastic materials (e.g. polyvinylchloride, polyethylene).            c) Requirements for gloves made from thermoplastic materials (e.g. polyvinylchloride, polyethylene).         </td> </tr> </tbody> </table>					Force at break in Newton			Surgical gloves a)	Examination/procedure gloves		b)	c)		<b>Throughout shelf life tested according to 5.2 and within 12 months of manufacture tested according to 5.3</b>	≥ 9,0	≥ 6,0	≥ 3,6	a) Requirements for all surgical gloves. b) Requirements for all examination gloves, except gloves made from thermoplastic materials (e.g. polyvinylchloride, polyethylene). c) Requirements for gloves made from thermoplastic materials (e.g. polyvinylchloride, polyethylene).			
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<b>5.3</b>	<b>Force at break after challenge testing</b>		<b>N</b>																		
<b>5.3.1</b>	Gloves packaged in unit packages or gloves taken from bulk packages shall be placed for a period of seven days at a temperature of $(70 \pm 2)$ °C in an oven as specified in ISO 188:2007, clause 4.		<b>N</b>																		
<b>5.3.2</b>	<b>Measure the force at break as described in 5.2.</b>		<b>P</b>																		
<b>6</b>	<b>Test report</b>		<b>P</b>																		
	Any test report shall include at least the following information:		<b>P</b>																		
	a) reference to this part of EN 455;		<b>P</b>																		
	b) the type of glove and the manufacturing batch code;		<b>P</b>																		
	c) the name and address of the manufacturer or distributor and test laboratory, if different;		<b>P</b>																		
	d) the date of testing performed;		<b>P</b>																		
	e) the test results.		<b>P</b>																		
<b>7</b>	<b>Labelling</b>		<b>N</b>																		
	In addition to labelling requirements defined in other parts of EN 455 manufacturers shall label the glove and/or the packaging with the date of manufacture in accordance with EN ISO 15223-1:2012 and EN 1041:2008+A1:2013. Date of manufacture is defined as the packaging date.		<b>N</b>																		

<b>EN 455-3:2015</b>			
<b>Clause</b>	<b>Requirement Test</b>	<b>Result-Remark</b>	<b>Verdict</b>
<b>1</b>	<b>Scope</b>		<b>P</b>
	This part of EN 455 specifies requirements for the evaluation of biological safety for medical gloves for single use. It gives requirements for labelling and the disclosure of information relevant to the test methods used.		<b>P</b>
<b>2</b>	<b>Normative references</b>		<b>N</b>
	The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.		<b>N</b>
<b>3</b>	<b>Terms and definitions</b>		<b>P</b>
	For the purposes of this document, the following terms and definitions apply.		<b>P</b>
<b>3.1</b>	<b>chemicals</b>		<b>P</b>
	substances added or formed during any step of the manufacturing process or in storage which may be available in the final product		<b>P</b>
<b>3.2</b>	<b>endotoxins</b>		<b>P</b>
	lipo-polysaccharides originating from the outer cell-membrane of Gram-negative bacteria		<b>P</b>
<b>3.3</b>	<b>powder</b>		<b>P</b>
	all water insoluble material on the surface of a glove that is removed by washing under the conditions of the test		<b>P</b>
<b>3.4</b>	<b>process limit</b>		<b>N</b>
	highest value likely to be encountered for a validated manufacturing process		<b>N</b>
<b>3.5</b>	<b>proteins, allergenic</b>		<b>N</b>
	proteins capable of causing a type I allergic reaction		<b>N</b>
<b>3.6</b>	<b>proteins, leachable</b>		<b>N</b>
	aqueous proteins and peptides extractable from the final product		<b>N</b>
<b>3.7</b>	<b>pyrogens</b>		<b>N</b>
	substances creating fever in rabbits which can be related to fever and other adverse reactions in humans		<b>N</b>



<b>EN 455-3:2015</b>			
<b>Clause</b>	<b>Requirement Test</b>	<b>Result-Remark</b>	<b>Verdict</b>
<b>4</b>	<b>Requirements</b>		<b>P</b>
<b>4.1</b>	<b>General</b>		<b>P</b>
	EN ISO 10993-1:2009 describes the general principles governing the biological evaluation of medical devices and shall be used to select the appropriate tests as described in other parts of the series. Based on EN ISO 10993-1:2009 medical gloves are classified as limited contact duration surface devices and require compliance to EN ISO 10993-5:2009 and EN ISO 10993-10:2013.		<b>P</b>
	The classification of medical gloves according to EN ISO 10993-1:2009 should not be confused with the definitions provided in the medical device directives for these products.		<b>P</b>
	A risk management process in accordance with EN ISO 14971:2012 shall be established.		<b>P</b>
<b>4.2</b>	<b>Chemicals</b>		<b>P</b>
	Gloves shall not be dressed with talcum powder (magnesium silicate).		<b>P</b>
	The manufacturer shall disclose, upon request, a list of chemical ingredients either added during manufacturing or already known to be present in the product such as accelerators, antioxidants and biocides that are known to cause adverse health effects based on current data.		<b>P</b>
	Upon request the manufacturer shall provide evidence of the steps taken to reduce the risk to the end-user of exposure to chemicals used in the manufacturing process which, based on current data, are known to cause adverse health effects.		<b>N</b>
	Manufacturers may only declare the absence of a substance if the substance is not used in any part of the manufacturing process. No compounds shall be used in the manufacture of the product that is known to form a substance that is subject of such a declaration.		<b>N</b>
<b>4.3</b>	<b>Endotoxins</b>		<b>P</b>
	The manufacturer shall monitor the endotoxin contamination of sterile gloves using the test method specified in 5.1 if the gloves are labelled with 'low endotoxin content'. For such labelled gloves the		<b>P</b>

<b>EN 455-3:2015</b>			
<b>Clause</b>	<b>Requirement Test</b>	<b>Result-Remark</b>	<b>Verdict</b>
	endotoxin content shall not exceed the limit of 20 endotoxin units per pair of gloves.		<b>P</b>
<b>4.4</b>	Powder-free gloves		<b>P</b>
	For powder-free gloves the total quantity of powder residues determined according to the test method under 5.2 shall not exceed 2 mg per glove. Any glove containing more than 2 mg powder is a powdered glove.		<b>P</b>
<b>4.5</b>	Proteins, leachable		<b>P</b>
	The manufacturer shall strive to minimize the leachable protein level.		<b>P</b>
	The manufacturer shall monitor the process limit of leachable protein in the finished gloves containing natural rubber latex by the method specified in 5.3 and described in Annex A. The documentation of these results shall be retained. The results of the test and applied test method shall be made available on request.		<b>P</b>
<b>4.6</b>	Labelling		<b>P</b>
	In addition to the labelling specified in EN 1041: 2008 + A1:2013 and the relevant symbols given in EN ISO 15223-1:2012, the following requirements apply:		-
	a) medical gloves containing natural rubber latex shall be labelled on the packaging of at least the smallest packaging unit with the EN ISO 15223-1:2012 symbol for latex (reference number 5.4.5).		<b>P</b>
	The labelling shall include the following or equivalent warning statement together with the symbol (Product) contains natural rubber latex which may cause allergic reactions, including anaphylactic responses;		<b>N</b>
	b) the labelling shall include a prominent indication of whether the glove is powdered or powder-free;		<b>P</b>
	c) sterile powdered gloves shall be labelled with the following or equivalent: 'CAUTION: Surface powder shall be removed aseptically prior to undertaking operative procedures in order to minimize the risk of adverse tissue reactions;		<b>P</b>
	d) for any medical glove containing natural rubber		<b>N</b>

<b>EN 455-3:2015</b>			
<b>Clause</b>	<b>Requirement Test</b>	<b>Result-Remark</b>	<b>Verdict</b>
	latex the product labelling shall not include:		N
	-any term suggesting relative safety, such as low allergenicity, hypoallergenicity or low protein;		N
	-any unjustified indication of the presence of allergens;		N
	e) if the manufacturer labels the gloves with the protein content, the process limit, measured as specified in 5.3 shall be given.		N
<b>5</b>	<b>Test methods</b>		<b>P</b>
<b>5.1</b>	<b>Endotoxins</b>		<b>P</b>
	Except where non-removable interferences in the Limulus Amoebocyte Lysate (LAL) procedures are present, selection, validation and use of technique shall be as described in the European Pharmacopoeia, Monograph 2.6.14, "Bacterial Endotoxins". The results shall be expressed in endotoxin units (E.U.) per pair of gloves.		<b>P</b>
	The minimum number of pairs of gloves recommended to be tested in relation to the number of items in the batch are two pairs of gloves for a batch size under thirty, three pairs of gloves for a batch size thirty to one hundred, and 3 % of a batch above size one hundred, up to a maximum of ten pairs of gloves per batch.		<b>P</b>
	The outside surface of a pair of gloves is extracted with 40 ml of endotoxin-free water (Water LAL, European Pharmacopoeia, for not less than 40 min and not more than 60 min at a temperature between 37 °C and 40 °C in a way to ensure that all surfaces come into contact with the extraction medium. The extract is centrifuged, if necessary, for 15 min at 2 000 g to remove particles after which the liquid component is decanted and tested for endotoxin immediately afterwards.		<b>P</b>
<b>5.2</b>	<b>Powder</b>		<b>N</b>
	The test method for the determination of powder residues described in EN ISO 21171:2006, Clauses 7 and 9 shall be used.		<b>N</b>
<b>5.3</b>	<b>Proteins, leachable</b>		<b>N</b>
	The test method for the analytical determination of leachable protein shall be the modified Lowry		<b>N</b>

<b>EN 455-3:2015</b>			
<b>Clause</b>	<b>Requirement Test</b>	<b>Result-Remark</b>	<b>Verdict</b>
	method given in Annex A or a suitably validated method which has been correlated against the modified Lowry method.		<b>N</b>
<b>6</b>	<b>Test report</b>		<b>P</b>
	The test report shall include at least the following information:		<b>P</b>
	— reference to this part of EN 455;		<b>P</b>
	— the type of gloves and the manufacturing batch code;		<b>P</b>
	— the name and address of the manufacturer or distributor and of the test laboratory, if different;		<b>P</b>
	— the date of the testing performed;		<b>P</b>
	— the description of the test method applied;		<b>P</b>
	— the test results.		<b>P</b>

<b>EN 455-4:2009</b>			
<b>Clause</b>	<b>Requirement Test</b>	<b>Result-Remark</b>	<b>Verdict</b>
<b>1</b>	<b>Scope</b>		<b>P</b>
	This part of EN 455 specifies requirements for shelf life for medical gloves for single use. It also specifies the requirements for labelling and the disclosure of information relevant to the test methods used.		<b>P</b>
	This European Standard applies to existing, new and significantly changed designs. Existing designs that do not currently have ageing data available should generate that data within a reasonable period of time.		<b>N</b>
	This European Standard does not specify the size of a lot. Attention is drawn to the difficulties that can be associated with the distribution and control of very large lots. The recommended maximum individual lot size for production is 500 000.		<b>N</b>
<b>2</b>	<b>Normative references</b>		<b>N</b>
	The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.		<b>N</b>
<b>3</b>	<b>Terms and definitions</b>		<b>P</b>
	For the purposes of this document, the following terms and definitions apply.		<b>P</b>
<b>3.1</b>	<b>Arrhenius equation</b>		<b>P</b>
	relation between the activation energy (EA), the absolute temperature (T), and the rate constant of a degradation reaction [k(T)]		<b>P</b>
<b>3.2</b>	<b>consumer package</b>		<b>P</b>
	package, intended for distribution to a consumer, containing loose gloves or individual pairs of gloves		<b>P</b>
<b>3.3</b>	<b>expiry date</b>		<b>N</b>
	stated date after which the gloves shall not be used		<b>N</b>
<b>3.4</b>	<b>lot</b>		<b>N</b>
	collection of gloves of the same design, colour, shape, size and formulation, manufactured at essentially the same time, using the same process, raw materials of the same specifications, common equipment and packed in the same type of individual container		<b>N</b>

<b>EN 455-4:2009</b>			
<b>Clause</b>	<b>Requirement Test</b>	<b>Result-Remark</b>	<b>Verdict</b>
<b>3.5</b>	<b>shelf life</b>		<b>N</b>
	time from date of manufacture to the claimed expiry date		<b>N</b>
<b>3.6</b>	<b>significant change</b>		<b>N</b>
	change that could reasonably be expected to impact the safety or effectiveness of a medical device		<b>N</b>
<b>3.7</b>	<b>threshold value</b>		<b>N</b>
	maximum or minimum value for a property being tested		<b>N</b>
<b>4</b>	<b>Requirements</b>		<b>P</b>
<b>4.1</b>	<b>General</b>		<b>P</b>
	Medical gloves shall comply with the requirements of the EN 455 series of standards until the end of their stated shelf life provided they are stored according to the instructions supplied by the manufacturer.		<b>P</b>
	Manufacturers shall test the properties that are reasonably expected to alter over the shelf life of the product. These properties shall include, but are not limited to, force at break, freedom from holes and, in the case of sterile gloves, pack integrity. This European Standard defines the methods to determine shelf life of medical gloves before any new product or products for which there has been a significant change to formulation or process can be marketed.		<b>P</b>
	Since it is impracticable to complete real time ageing studies before introducing products to the market, accelerated stability studies based on kinetic principles can be used to assign a provisional shelf life. Such provisional shelf lives assigned shall be verified by real time studies.		<b>P</b>
	Shelf life claims based on accelerated ageing shall not exceed three years. Data supporting the shelf life claims made by the manufacturer shall be made available on request.		<b>P</b>
<b>4.2</b>	<b>Shelf life and resistance to degradation</b>		<b>P</b>
	Before a new or significantly modified product is placed on the market this European Standard requires:		<b>-</b>
	-a completed real time study as described in 5.1 to determine shelf life or		<b>P</b>

<b>EN 455-4:2009</b>			
<b>Clause</b>	<b>Requirement Test</b>	<b>Result-Remark</b>	<b>Verdict</b>
	-a real time study as described in 5.1 to determine shelf life shall have commenced and an accelerated ageing study as described in 5.2 shall have been completed.		<b>P</b>
	It is recommended that the shelf life should be determined at the specific storage conditions specified for the product by the manufacturer (e.g. 25 °C). The manufacturer shall state the temperature along with the shelf life or expiry date. Accelerated ageing studies (5.2) shall be carried out on gloves from the same production lots as used for real time determination of shelf life (5.1).		<b>P</b>
<b>4.3</b>	<b>Product changes</b>		<b>N</b>
	Whenever there is any significant change to the product the manufacturer shall re-determine shelf life.		<b>N</b>
<b>4.4</b>	<b>Labelling</b>		<b>P</b>
	At the end of the shelf life the labelling shall remain readable according to EN 1041.		<b>P</b>
<b>4.5</b>	<b>Sterile barrier integrity</b>		<b>P</b>
	For sterile products the requirements of EN ISO 11607 series apply. Attention is drawn to the maintenance of the sterility for the given shelf life of the product.		<b>P</b>
<b>4.6</b>	<b>Storage conditions</b>		<b>N</b>
	Manufacturers shall provide storage instructions to the end user. These may be printed on the consumer package or supplied in an accompanying document.		<b>N</b>
<b>5</b>	<b>Test methods</b>		<b>P</b>
<b>5.1</b>	<b>Real time shelf life determination</b>		<b>P</b>
	The test method for the determination of shelf life using real time studies shall be that given in Annex A or a suitably validated method that has been shown to be equivalent to Annex A.		<b>P</b>
	If the real time data indicates a shorter shelf life than that claimed on the basis of accelerated ageing the manufacturer shall notify the relevant regulatory authorities. The manufacturer shall change the shelf life claims for the product to one based upon the real time study. For gloves placed on the market, real time stability studies shall be completed for the full		<b>N</b>

<b>EN 455-4:2009</b>			
<b>Clause</b>	<b>Requirement Test</b>	<b>Result-Remark</b>	<b>Verdict</b>
	period of the shelf life claim.		N
<b>5.2</b>	<b>Accelerated shelf life determination</b>		P
	Pending the completion of real time studies, accelerated stability studies shall be used to estimate the shelf life. Examples of methods for accelerated		P
	studies and data analysis are provided in Annex B. Data generated from such studies shall support the claim that the gloves fulfil the requirements in Clause 4 for the duration of the labelled shelf life at temperature as determined by the manufacturer.		P
<b>6</b>	<b>Test report</b>		<b>P</b>
	The test report shall contain at least the following information:		-
	a) Reference to the appropriate standards;		<b>P</b>
	b) Sample details: 1) Complete identification of the material tested; 2) Dimensions and method of the preparation of the test pieces, with reference to relevant European Standards; 3) Selected properties, with reference to relevant European Standards; 4) Threshold value of the selected property; 5) Times and temperatures of the conditioning of test pieces;		<b>P</b>
	c) Details of the ageing conditions;		<b>P</b>
	d) Test data and analysis according to the relevant standards;		<b>P</b>
	e) Confirmed shelf life claim.		<b>P</b>



Photo 1

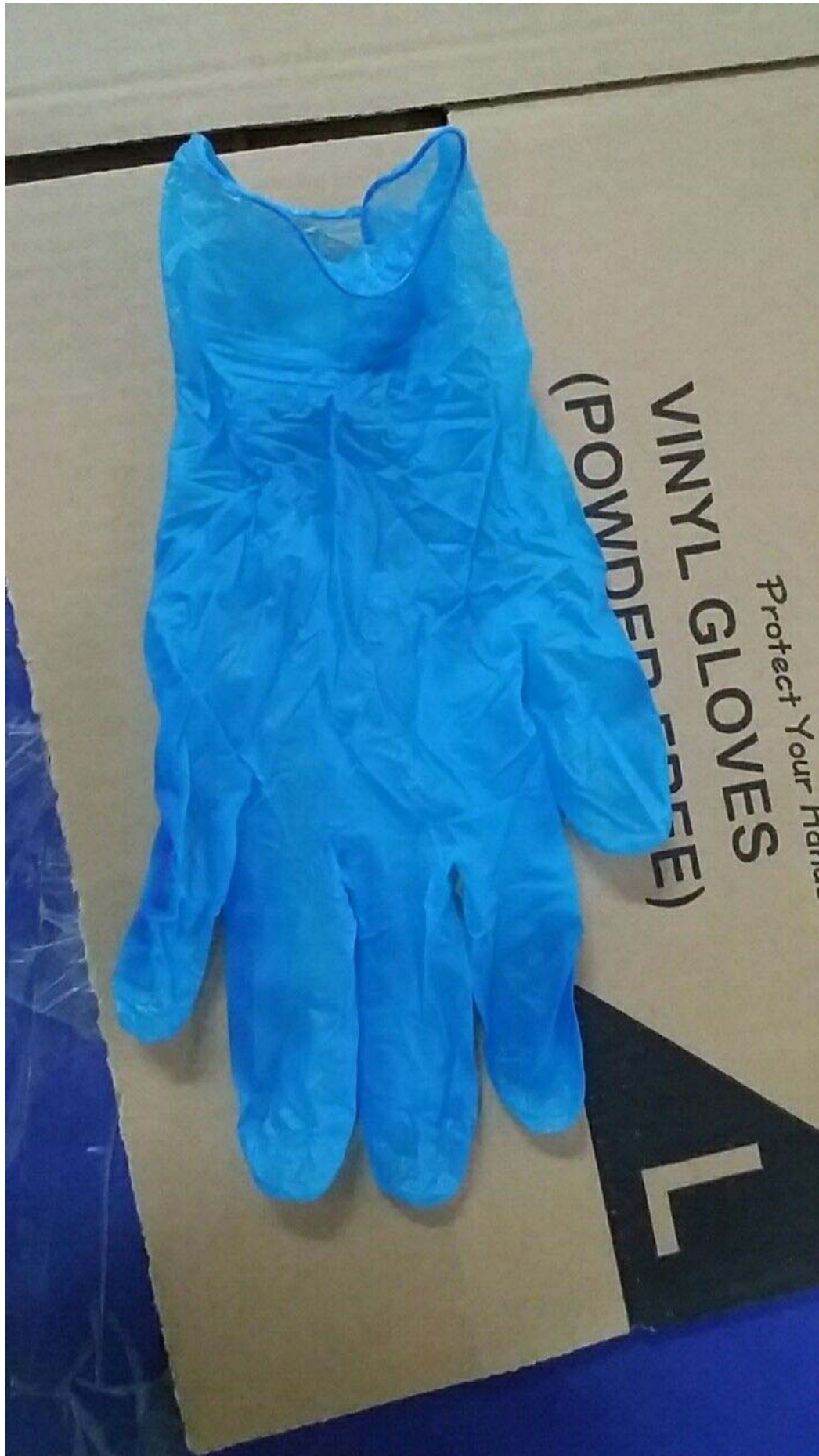


Photo 2

