

# Examination glove standards explained (1)

## Medical device regulations

The Medical Devices Directive 93/42/EEC and Medical Devices Regulation (EU) 2017/745 are the principal European legislation governing our range of medical gloves.

They are concerned with ensuring that products are safe for patients and users, are manufactured in suitable environments, and that products meet the appropriate product standards. The main standards for examination gloves are listed below:

### EN455

Is a series of standards that define gloves that meet the requirements of the Medical Devices Directive 93/42/EEC and are suitable for use in medical procedures.

The regulations and these standards are primarily concerned with protecting the patient.

This standard contains parts 1 - 4 which need to be complied with, please visit the 'RESOURCES' section of [unigloves.co.uk](http://unigloves.co.uk) for details on EN455 parts 1 - 4.

#### Part 1

##### Requirements and testing for freedom from holes

Gloves must pass this test in order to prove that they are an effective barrier against micro-organisms.

#### Part 3

##### Requirements and testing for biological evaluation

Includes tests for potentially hazardous materials that may affect the wearer or be transferred to a patient. These materials include:

**Endotoxins:** toxic materials left behind by certain bacteria which can be harmful to humans.

**Latex proteins:** proteins and enzymes in natural rubber latex which can cause an allergic (Type I) reaction in some users.

**Chemical residues:** accelerators are used to improve the strength of some gloves, but can cause allergic (Type IV) reactions in some users.

**Powder:** powders added to some gloves assist in donning, but can cause reactions in some individuals.

A powder free medical glove should have a powder level of <2mg per glove.

#### Part 2

##### Requirements and testing for physical properties

This standard includes tests for glove dimension and physical strength.

Gloves must have different strengths depending on the material they are manufactured from, reflecting the different properties of each material.

	Force at break (Newtons)
Latex	6.0
Nitrile	6.0
Vinyl	3.6

#### Part 4

##### Determination of shelf-life

This standard specifies tests for determining how long a glove will be fit for use when stored in warehouse or end-user store rooms. Five years is the maximum shelf-life that can be claimed for medical gloves.

find out more at [unigloves.co.uk/resources](http://unigloves.co.uk/resources)

# Examination glove standards explained (2)

## Personal Protective Equipment regulations

Personal Protective Equipment (PPE) is designed to protect the user from hazards, the principal European legislation are the PPE Directive 89/686/EEC and the PPE Regulation (EU) 2016/425.

Our gloves certified under these regulations protect the user against common hazards found in industry: micro-organisms and chemical hazards. The main standards for gloves certified as PPE are listed below.

### EN420

Defines the general requirements of gloves to comply with the PPE regulations.

These regulations and this standard is primarily concerned with **protecting the wearer**.

### EN374

Defines the requirements of gloves to protect against certain chemicals and micro-organisms.

The regulations and these standards are primarily concerned with protecting the wearer. This standard contains parts 1 - 5 depending on the glove performance, please visit the 'RESOURCES' section of unigloves.co.uk for details on parts 1 - 5.

#### Part 1

##### Terminology & performance requirements

This standard relates to the terminology and performance requirements for gloves protective against microorganisms and chemicals and is similar in scope to EN455 part 1.

#### Part 2

##### Determination of resistance to penetration

Certifies that the gloves protect against micro-organisms.



#### Part 3

##### Determination of resistance to permeation

Certifies that the gloves protect against certain chemicals.

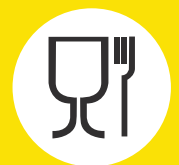
If the chemicals tested take more than 30 minutes to permeate the glove, fig. 1 is used, otherwise fig. 2 is used, indicating lower resistance.



### EN1186

#### Food safe

In conjunction with Articles in Contact with Food regulations, defines the requirements of gloves in contact with food.



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