Wright MILLNERS

2016

Examination glove standards explained (1)

MEDICAL DEVICE STANDARDS

The Medical Device Directive (93/42/EEC) is the principal piece of European legislation covering our range of medical gloves.

The Directive is concerned with ensuring that products are safe for patient 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

Certifies that gloves meet the requirements of the Medical Device Directive 93/42/EEC and are suitable for use in medical procedures.

The Directive and this standard is primarily concerned with protecting the patient.

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 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 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 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.

Examination glove standards explained (2)

PERSONAL PROTECTIVE EQUIPMENT STANDARDS

Personal Protective Equipment (PPE) is designed to protect the user from hazards, and as with the Medical Devices, the principal European legislation is an EU directive (89/686/EEC).

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

EN420

Certifies that the gloves meet the general requirements of the PPE Directive.

The PPE Directive and this standard is primarily concerned with protecting the wearer.

EN420

Certifies that gloves are protective against certain chemicals and micro-organisms.

The PPE Directive and this standard is primarily concerned with protecting the wearer.

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 microorganisms.

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
Certifies that chemicals and materials from the gloves will not be transferred into food.