Medical examination gloves

Be aware of what you purchase and use!

Correct use and choice of glove is essential for the protection of the caregiver and caretaker against risks. Users do not always have the full or required knowledge of the type of glove they use/purchase, in specific in relation to the specifics of the material, test results and the envisaged use of the glove by the manufacturer.

Personal protective equipment versus medical device
A glove for one time use can be divided into two categories:
Medical device This glove has to meet the requirements of the Medical Device Directive 93/42/EEG
Personal protective equipment This glove has to meet the requirements of the European Directive Personal Protective Equipment 89/686/EEG.

Medical examination gloves
A medical examination glove is classified as a class I medical device. A manufacturer of these products indicates that the gloves meet the essential requirements of Directive 93/42/EEG by way of self-assessment. As long as these requirements are met the gloves can be freely commercialized on the European market. The packaging of the gloves includes a CE marking without a number. Surgical gloves are categorized in a higher class as examination gloves and have to be assessed by a notified body.

Need to meet EN 455
The series of standards EN 455 contain specific requirements for medical gloves. These specific technical standards are harmonized with the legal requirements. This means that when a manufacturer complies with these standards, as a user you can go from there that the various legal requirements are covered. This makes it easier for users to assess whether any claims can be substantiated.

The national NEN expert group advises users to pay special attention to requirements of the standards series EN 455.

By requesting independent test results from the manufacturer, extra attention is paid to the quality of medical examination gloves. Based on these reports an informed decision can be taken with regard to purchase and use.

The standard EN 455 series provide a solid base to determine what requirements gloves should meet if they are commercialized on the European market.

Manufacturers carry out tests on a regular basis, regardless of the material of the glove.

Physical properties - Force at Break
The minimum tensile strength of an examination glove must be 6 Newton (for vinyl this is 3.6 Newton). It may be that fillers are used to reduce the cost price of a glove. In low doses, the physical properties of a glove are enhanced. Higher amounts of fillers however can result in a decrease in the elasticity and resistance to chemicals. The use of high amounts of fillers leads less rubber in the gloves, with all the possible risks.
Advice: Request the tensile performance of the gloves from the manufacturer.

Acceptable Quality Level (AQL)
The series of standards EN 455 allows an AQL of 1.5. This means that about 3% of all gloves also may contain pinholes, regardless of the material from which the glove is made. The majority of the holes are very small and therefore difficult to detect. For all gloves the same test methods and possible outcomes of the measurement apply.
Advice: choose the material of a glove on the basis of the intended application.

Allergy
In order to avoid allergies it is important to pay attention to specific warnings. It is likely that for thinner gloves which contain higher amounts of fillers as comparable products, additional chemicals are added during the manufacturing process. This is done to compensate the lack of raw material and is applied for every type of material. These added chemicals increase the risk on contact allergy type IV.

Furthermore, it is important to compare the content of protein and allergen and powder free / non-powder-free of different gloves with each other.
Advice: Compare packaging thoroughly, latex-free gloves can also contain contact allergens *. Request therefore a list of added chemicals and a test report of the chemical residues from the manufacturer.

Shelf Life

During the storage period a glove meets the essential requirements. After the expiration date gloves should not be used. The amount of fillers can affect the shelf life negative.

Advice: Ensure actively that there is no use of gloves after the expiration date.

Personal Protective Equipment Directive

It is possible that a glove meets simultaneously the requirements of the medical device directive and the requirements of the personal protective equipment directive. If this is indicated by the manufacturer, specific information available will be available. Many are gloves that protect against chemicals. According to the PPE Directive 89/686/EEC this type of gloves are classified under the category 'complex design' as chemical risks are classified as high risk. This type of gloves are tested by a 'Notified Body'. The CE-marking shall be accompanied by the recognition code of the notified body.

Advice: Request from the manufacturer tests, CE certification and the declaration of conformity conform to the Directive 89/686/EEC.

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* Occupational Diseases in Figures 2011, Dutch Centre for Occupational Health

FREE TRANSLATION