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Medical gloves for single use - Guidance for selection

Medizinische Einmalhandschuhe - Leitlinien für die Auswahl

Gants médicaux non réutilisables - Lignes directrices pour sélectionner des gants médicaux non réutilisables

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Medical gloves for single use - Guidance for selection

Gants médicaux non réutilisables - Lignes directrices pour sélectionner des gants médicaux non réutilisables

Medizinische Einmalhandschuhe - Leitlinien für die Auswahl

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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European foreword

This document (CEN/TR 16953:2017) has been prepared by Technical Committee CEN/TC 205 “Non-active medical devices”, the secretariat of which is held by DIN.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association.

This Technical Report gives information for use in the EN 455 series of standards. EN 455, *Medical gloves for single use,* which consists of the following parts:

— *Part 1: Requirements and testing for freedom from holes*

— *Part 2: Requirements and testing for physical properties*

— *Part 3: Requirements and testing for biological evaluation*

— *Part 4: Requirements and testing for shelf life determination*

Introduction

This Technical Report sets out guidance for users and choosers for selection, storage and use of gloves for medical applications.

Glove selection is technically complex and should be undertaken by suitably qualified professionals.

Medical gloves have been shown to be a barrier to agents responsible for the transmission of infections. In order to help ensure effectiveness, it is essential that the gloves fit properly, are free from holes, and have adequate physical properties over their entire shelf life to resist barrier failure during use. In addition it is important that adequate information is provided on any risks to the health of glove users or patients that use of the gloves can cause, e.g. allergic reactions. These issues are addressed in the EN 455 series.

EN Standards once mandated by the EU Commission are referred to as 'harmonized' and are binding on CEN Member States. Products which comply with harmonized standards are assumed to comply with relevant Essential Requirements. 'Horizontal' standards apply across a range of different types of product (e.g. sterility or labelling). 'Vertical' standards apply to a specific type of product e.g. medical gloves.

CE marking is a key indicator of a product's compliance with EU legislation and enables the free movement of products within the European market. By affixing the CE marking on a product, a manufacturer is declaring conformity with all legal requirements to achieve CE marking and therefore ensuring validity for that product to be sold throughout the EEA, the member states of the EU and European Free Trade Association countries - Iceland, Norway, Liechtenstein and Turkey. Further information regarding CE marking can be found in Annex C.

Single-use medical gloves fall into two main device classifications depending on degree of invasiveness of their use.

Non sterile Examination gloves are class I medical devices and are CE marked by the manufacturer without third party regulatory approval. They are usually, but not necessarily, ambidextrous and bulk-packed. Sterile examination gloves are class I sterile medical devices designed for short non-invasive aseptic procedures (generally less than 60 min) in patient care. They require regulatory approval for their sterility. Because they are intended for short procedures only, examination gloves are generally thinner, and less robust than surgical grade gloves. They are usually sold in a limited number of sizes. The force at break requirements for such gloves are specified at levels which are lower than for surgical gloves but are based on many years cumulative experience of minimum requirements needed to ensure acceptable performance in use. Values differ for different materials and are reflected in the requirements of EN 455-2. They are sold either powdered with donning powder or as 'powder free'. Powder free gloves may have surface treatments or added chemical agents to assist in easy donning.

Surgical gloves are class IIa medical devices and are designed for invasive procedures. CE marking requires approval of a Notified Body. They are sold sterile in a range of full and half sizes and packed in pairs of handed gloves. Packaging is normally in an easy peel pack that can deliver sterile inner wrapped gloves onto the sterile surgical field. Sterility is achieved by e.g. gamma or electron beam irradiation or by ethylene oxide treatment. Surgical gloves are sterilized to a sterility assurance level (SAL) of 10^{-6} (according to EN 556-1) which gives a one in a million probability of finding a non sterile device. Force at break requirements are more rigorous than for examination gloves and reflect the levels that can be achieved for the materials concerned balanced against other in-use factors such as comfort, dexterity and sensitivity of touch.

1 Scope

This Technical Report provides information for those choosing or using sterile and non-sterile gloves for medical applications based on a risk assessment. It deals with gloves worn primarily for the protection of the patient and glove user from biological cross contamination.

NOTE Gloves worn specifically for the protection of the glove user from e.g. chemical and biological hazards are covered by the EU-Directive on Personal Protective Equipment (PPE) and the related standards e.g. EN 16523-1, EN 374-2, EN 374-4, EN ISO 374-1 and EN ISO 374-5.

This document describes the rationale behind the requirements of the EN 455 series and explores the possible trade-offs in glove selection between the various factors which affect glove, physical properties, biocompatibility, comfort and sensitivity. The strengths and weaknesses of various alternative glove materials and the potential biological hazards presented by their use are also explored.

2 Normative references

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.

EN 455 (series), *Medical gloves for single use*

EN ISO 374-5, *Protective gloves against dangerous chemicals and micro-organisms - Part 5: Terminology and performance requirements for micro-organisms risks (ISO 374-5)*

EN ISO 10993-10, *Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization (ISO 10993-10)*

ISO 2859-1, *Sampling procedures for inspection by attributes — Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in the EN 455 series and the following apply.

3.1
EU Directives
3.1.1
MDD
MD Directive
(Medical Device Directive)
legal act of the European Union covering the requirements that apply to medical devices including gloves with a medical purpose in the patient environment

Note 1 to entry: Protection against chemicals such as disinfectants, chemotherapy drugs etc. or against mechanical risks is not considered to be a medical purpose.

Note 2 to entry: Prior to amendment by Directive 2007/47/EC, MD Directive did not apply to personal protective equipment covered by Directive 89/686/EEC. The principal intended purpose of the product was decisive for deciding whether either the PPE Directive or the MD Directive was applicable.

Note 3 to entry: The interpretative document of the European commission's services of August 2009 clarifies that products for which a manufacturer claims a double purpose (MD and PPE) are covered by the MD Directive.

In case of simultaneous application of MDD and PPE Directives the product need to undergo the conformity assessment procedures of both directives.

Note 4 to entry: The MDD will be superseded by the upcoming MDR (Medical Devices Regulation). For further information see www.eur-lex.europa.eu .

3.1.2
PPED
PPE Directive
(Personal Protective Equipment Directive)
legal act of the European Union covering the requirements that apply to any device worn or held by an individual for protection against one or more health and safety hazard

Note 1 to entry: PPE Directive covers only the safety of the glove user rather than the patient.

Note 2 to entry: Only a CE-mark approved by a notified body ensures compliance to PPE Directive category II and III.

Note 3 to entry: The Directive 89/686/EEC will be superseded by the PPER (Personal Protective Equipment Regulation 2016/425). For further information see http://eur-lex.europa.eu/homepage.html

3.2
single-use medical gloves
device intended to be used once only for a single patient

3.3
elastomer/elastic polymer
macromolecular material which returns rapidly to approximately its initial dimensions and shape after substantial deformation by a weak stress and release of the stress

[SOURCE: ISO 1382:2012 modified, the heading "/elastic polymer" was added]

3.4
specific glove raw materials
3.4.1
natural rubber
NR
solid material with elastic properties obtained from the botanic source *Hevea brasiliensis*

Note 1 to entry: Cis-1,4-polyisoprene is the main constituent of NR.

[SOURCE: EN 923:2015, 2.3.15]

3.4.2
synthetic rubber
manufactured elastomeric material which in comparison to natural rubber, may have varying degrees of elasticity and hardness

Note 1 to entry: For further information see 5.1.2.

3.4.3
thermoplastics
plastics that are capable of being repeatedly softened by heating and hardened by cooling through a temperature range characteristic of the plastics and, in the softened state, of being repeatedly shaped by flow into articles by moulding, extrusion or forming

3.4.4
latex
colloidal aqueous dispersion of a polymeric material

[SOURCE: EN ISO 472:2013, 2.529]

Note 1 to entry: This may be naturally occurring as in e.g. natural rubber latex, the milky extract from the rubber plant, or may be manufactured, as in dispersions of synthetic polymers in water, e.g. polychloroprene latex, or as in latex paints which are pigments bound by polymeric resins dispersed in water. The term "latex glove" is commonly understood to refer to natural rubber gloves but it can also apply to synthetic rubber gloves as these are produced from a latex. There is therefore potential for misinterpretation.

4 Considerations in glove selection

4.1 General

Those wishing to select medical gloves for specific procedures will do so, on the basis of a risk assessment of the potential hazards to patient and glove user.

The risk assessment will include:

— the risks associated with cross contamination (see 4.2);

— the length of the procedure/comfort/durability required;

— degree of manual dexterity envisaged e.g. procedures where thicker gloves or/and double gloving is recommended to provide added protection will be at the expense of reduced sensitivity and comfort. Micro surgery may require a thinner glove affording greater sensitivity at the expense of durability;

— physical challenge of the procedure to the glove material e.g. handling sharp or potentially damaging instruments/materials; and

— biocompatibility issues, i.e. the potential for allergic reaction by the glove user or patient and risk of contamination of either by extractable/leachable glove components (see 4.3).

The following hazards are addressed by the EN 455 series:

— biological organism material (fungi, bacteria, viruses);

— non biocompatibility.

The following hazards are not addressed by the EN 455 series:

— chemical permeation or degradation e.g. by disinfectants or chemotherapy drugs;

— physical and mechanical damage e.g. by sharp instruments, needles.

Gloves that offer protection against the above hazards should comply with the PPE Directive and the related standards e.g. EN 16523-1, EN 374-2, EN 374-4, EN ISO 374-1 and EN ISO 374-5. Medical gloves required to perform this additional function should conform to the relevant PPE Directive and related standards.

Guidance for selection of gloves with respect to the intended use and risk is given in Figure 1. Where conformity with more than one directive is claimed this will be indicated by the affixing of the CE mark with reference to the relevant directives.

Additional information can be found in Annex B.

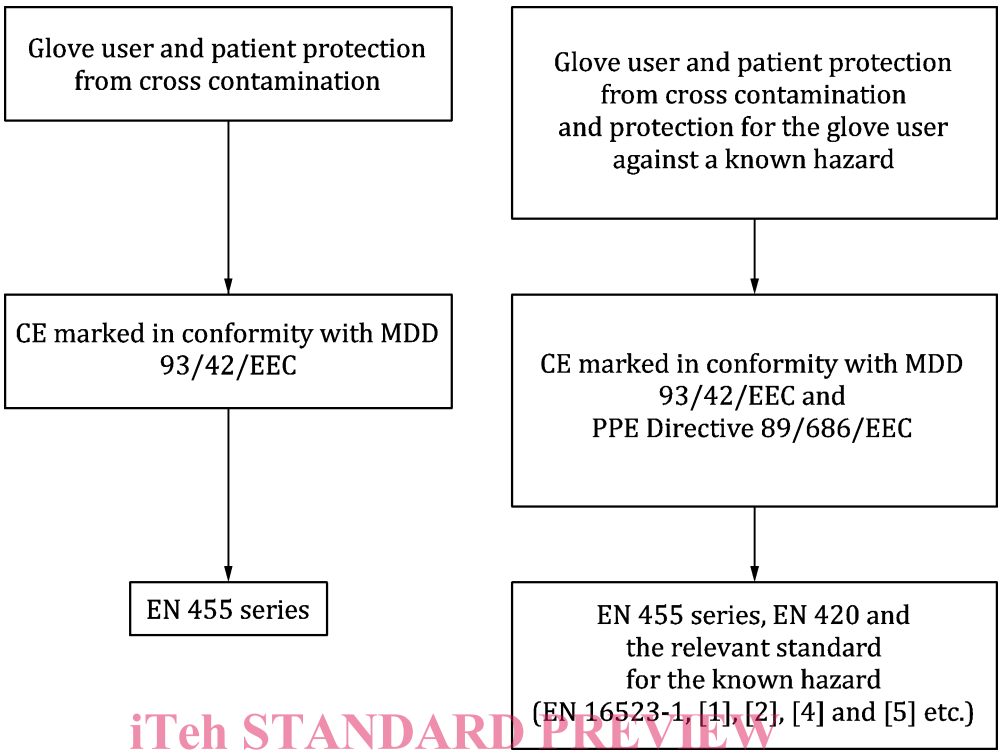

Figure 1 — Guidance for selection of gloves with respect to the intended use and risk

4.2 Cross contamination risk

4.2.1 General

The risk of cross contamination between medical glove user and patient varies with factors such as: infection status of patient, degree of exposure to body fluids, status of patient immune system, degree of invasiveness of procedure, barrier effectiveness of gloves, length of procedure, likelihood of physical damage to gloves etc.. These factors should be included in the risk assessment procedure to choose an appropriate glove material and properties.

Any glove material is required to be tested to confirm that it is a barrier to microorganisms (bacteria, viruses, fungi). This is confirmed by the bacteriophage test as described in EN ISO 374-5 or equivalent (e.g. ASTM F1671-08). The effective barrier properties of any finished glove will be dependent on the glove being intact and this is dependent on the quality of its manufacture (freedom from holes, physical properties). These two factors are covered by EN 455-1 and EN 455-2.

4.2.2 Freedom from holes

Only an intact film will act as a barrier to microorganisms. Consequently, testing for freedom from holes is an appropriate test to demonstrate barrier properties to microorganisms including viruses. Requirements and testing for freedom from holes is considered in EN 455-1 which describes the testing necessary to establish the required degree of freedom from holes as measured by a water tightness test. The water tightness test is the reference test for detection of holes.

NOTE 1 A manufacturer's claim of 100 % air inflation testing is only of value if accompanied by visual inspection to detect imperfections which could lead to rapid hole formation on extension, e.g. bubbles in finger crotches. Tiny holes in areas which do not stretch greatly with air inflation will not be detected by this test. Any claim based on electronic testing akin to that used in condom quality assurance is also not reliable due to