SLOVENSKI STANDARD
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Medicinske rokavice za enkratno uporabo - 5. del: Izločljivi kemični ostanki

Medical gloves for single use - Part 5: Extractable chemical residues

Medizinische Handschuhe zum einmaligen Gebrauch - Teil 5: Extrahierbare chemische Rückstände

Gants médicaux non réutilisables - Partie 5: Résidus de substances chimiques extractibles

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Medical gloves for single use - Part 5: Extractable chemical residues

Medizinische Handschuhe zum einmaligen Gebrauch - Teil 5: Extrahierbare chemische Rückstände

This draft European Standard is submitted to CEN members for enquiry. It has been drawn up by the Technical Committee CEN/TC 205.

If this draft becomes a European Standard, CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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European foreword

This document (prEN 455-5:2023) has been prepared by Technical Committee CEN/TC 205 “Non-active medical devices”, the secretariat of which is held by DIN.

This document is currently submitted to the CEN Enquiry.

This document has been prepared under a Standardization Request given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s) / Regulation(s).

For relationship with EU Directive(s) / Regulation(s), see informative Annex ZA, which is an integral part of this document.

EN 455 consists of the following parts under the general title “Medical gloves for single use”:

— 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;

— Part 5: Extractable chemical residues.

A list of all parts in a series can be found on the CEN website.

Introduction

Adverse reactions to residual chemicals present in medical gloves have been reported over many years in variable rates of prevalence. These chemicals are part of the manufacturing process including but not limited to accelerators, activators, antioxidants, or donning aids. Reactions range from dermal irritation to contact dermatitis including type IV allergic responses. These effects are localised to the area of contact with the offending chemicals and unlike type I allergic reactions do not show any systemic non-localised effects. Though they are potentially career altering, they do not escalate to more serious life-threatening responses.

Such adverse reactions are possible with gloves made of any material whose manufacture involves use of chemical additives at any stage of the manufacturing process. Factors which contribute to the risk of reaction include

— the concentration and ease of release of the chemicals;

— the duration and frequency of skin contact with gloves; and

— the occlusive nature of the glove/skin interaction during glove use.

The EN ISO 10993 series specifies requirements and test methods for biological evaluation of medical devices. Historically EN ISO 10993-10 has used animal testing to determine irritation and sensitisation potential of products which related to their residual chemical content. This is a fairly crude screen and simply prevents poor quality products containing excessive levels of bioavailable chemicals from reaching the market. It can neither predict changes in chemical availability during product shelf life nor potential for sensitisation or provocation of allergic responses in users.

This document gives requirements for quantitative measurement of potentially harmful residual extractable chemicals in medical gloves as part of a risk management process, in accordance with the EN ISO 10993 series.

1 Scope

This document provides requirements for label information about chemicals used in product manufacture, particularly potentially allergenic substances employed and remaining in medical gloves. It also provides information on extraction media, methods of extraction and quantitative assay of residual chemicals.

This document does not provide information on the allergenic potential or safety to the user of any product. This is expected to be assessed in the light of all available toxicity and biocompatibility data on the products concerned as part of a risk management process.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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.

FprEN 455-3:2023,[1] *Medical gloves for single use — Part 3: Requirements and testing for biological evaluation*

EN ISO 10993-1:2020, *Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2018, including corrected version 2018-10)*

EN ISO 14971:2019, *Medical devices - Application of risk management to medical devices (ISO 14971:2019)*

EN ISO 20417:2021, *Medical devices - Information to be supplied by the manufacturer (ISO 20417:2021, Corrected version 2021-12)*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp/

— IEC Electropedia: available at https://www.electropedia.org/

3.1
allergenic
having the potential to provoke an allergic response

Note 1 to entry: The allergens of concern in this document are those that provoke type IV delayed contact dermatitis reactions.

3.2
chemicals
substances added or formed during any step of the manufacturing process, including sterilisation, or in storage which may be available in the final product

Note 1 to entry: These can include but are not limited to lubricants, chemical coatings and sterilizing agents. Several chemical ingredients are commonly used during processing of gloves, some of them are known to cause type IV allergic reactions. The type and amount of residual chemicals added and finally present are variable

[1] EN 455-3:2023 is planned to be published 2023-10.

Note 2 to entry: For glove materials curing agents are used. These are chemicals which cause crosslinking to occur. The curing agent is most commonly sulfur, or can be a sulfur donor in a process known as vulcanisation. Examples of other curing agents would include those employed in peroxide or radiation curing.

[SOURCE: EN 455-3:2015, definition 3.1 – modified, " , including sterilisation, " within the definition and Note 2 to entry added]

3.3
curing agent
chemical which causes crosslinking to occur

Note 1 to entry: For glove materials, this is commonly sulfur, or may be a sulfur donor in a process known as vulcanisation. Examples of other curing agents would include those employed in peroxide or radiation curing.

3.4
chemicals leachable
substances which can be extracted from the product by contact with body fluid (sweat) or other liquids

3.5
extraction media
liquids used to extract residual chemicals from the glove

Note 1 to entry: These can range from aggressive organic solvents which can achieve exaggerated extraction of the target chemicals but not degrade the glove material or more biologically related mild solvent/aqueous/vegetable oil-based solutions which are used to mimic the leaching effect of wearer body fluids in glove usage.

3.6
exaggerated extraction
extraction that is intended to result in a greater amount of a chemical constituent being released as compared to the amount generated under the simulated conditions of use

Note 1 to entry: It is important to ensure that the exaggerated extraction does not result in a chemical change of the material.

[SOURCE: EN ISO 10993-12:2021, definition 3.4]

3.7
exhaustive extraction
extraction conducted until the amount of extractable material in a subsequent extraction is less than 10 % by gravimetric analysis of that detected in the initial extraction

[SOURCE: EN ISO 10993-12:2021, definition 3.5 – modified, Note to entry has been deleted.]

3.8
simulated-use extraction
extraction conducted to demonstrate compliance with the requirements of ISO 10993-12 by evaluating leachable material levels available to the patient or user from devices during the routine use of a device, using an extraction method that simulates product use

[SOURCE: EN ISO 10993-12:2021, definition 3.14 – modified, "this part of ISO 10993" has been replaced with "ISO 10993-12" and the Note to entry has been deleted]

3.9
contact allergen
substance known or suspected to cause Type IV allergy

3.10
accelerator
activator
chemical which catalyses the chemical reactions necessary to bring about curing (vulcanisation)

Note 1 to entry: A catalyst is a substance which speeds up a chemical reaction without being consumed by the process.

4 Requirements

4.1 General

EN ISO 10993-1:2020 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.

NOTE Based on EN ISO 10993-1:2020, medical gloves are classified as surface devices with limited contact duration. EN ISO 10993-1:2020 combines the review and evaluation of existing data from all resources with, where necessary, the selection and application of additional tests, thus enabling a full evaluation to be made of the biological responses to each medical device, relevant to its safety in use. The classification of medical gloves according to EN ISO 10993-1:2020 cannot be confused with the definitions provided in the medical device regulation for these products.

A risk management process in accordance with EN ISO 14971:2019 shall be established.

4.2 Chemicals

A list of chemicals which are relevant contact allergens often found in medical gloves is provided in Annex C.

The manufacturer shall disclose a list of chemicals used in all stages of the manufacturing process which, based on current state of the art, are known or suspected to be contact allergens, i.e. to cause Type IV allergy. These may include but are not limited to chemicals such as curing agents (vulcanising agents), accelerators, stabilisers, surfactants, antioxidants, plasticisers and biocides. Examples of such chemicals are given in Annex C.

The manufacturer shall provide evidence of the steps taken to reduce the risk to the end-user of exposure to such chemicals. Manufacturers may only declare the absence of a substance if the substance is not used in any part of the manufacturing process. No compound shall be used in the manufacture of the product that is known to form a substance that is subject of such a declaration.

FprEN 455-3:2023 specifies requirements for chemicals, which should also be complied with.

4.3 Chemicals leachable

Manufacturers shall provide information on the levels of extractable contact allergen present in their gloves both by exhaustive extraction and simulated-use extraction. The manufacturer shall validate their processes to ensure the process limit of leachable chemicals in the finished gloves by the extraction methods outlined in 5.1 and described in Annexes A and B, and using fully validated methods for quantitative measurement. The documentation of these results shall be retained. The results of the test and applied test method shall be made available on request.

4.4 Labelling

In addition to the labelling specified in EN ISO 20417:2021 and FprEN 455-3:2023, information of each of the leachable chemicals of concern shall be provided either on primary packaging or in an accompanying document. The claimed chemical content of the gloves shall be the process limit as measured according to 5.3. If simulated-use extraction data is provided it shall be demonstrated that this is based on the worst-case scenario following extreme temperature accelerated storage of gloves for 7 days at 0°C.

5 Test methods

5.1 General

All test methods used to show conformity to this document shall be validated and documented by the laboratory performing the test.

Sources of guidance on test method validation can be found in Annex D.

5.2 Chemicals leachable

The test method for the analytical determination of leachable chemicals shall specify the following parameters:

— name and CAS number[2] of chemical and function, e.g. accelerators, activators, antioxidants or donning aids;

— means of extraction, whole glove, glove inner surface or glove pieces;

— extraction medium, organic solvent, physiological saline solution, simulated sweat, vegetable oil;

— time and temperature of extraction;

— means of agitation;

— preconditioning temperature and duration;

— separation and assay method, e.g. TLC, GC, HPLC, MS, UV.

5.3 Extraction and assay methods

Extraction methods are described in Annexes A and B. Examples of suitable assay methods are shown in Annexes E, F, G and H.

6 Test report

The test report shall include at least the following information:

— reference to this part of EN 455;

— the type of gloves and the manufacturing batch code;

— the name and address of the manufacturer or distributor and of the test laboratory, if different;

— the date when the testing was performed;

[2] CAS number means Chemical Abstracts Service Registry Number.

— the description of the test method applied;

— the test results.