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Interested committees:

Title: Draft BS EN 455-5 BS Medical gloves for single use. Part 5: Extractable chemical residues.

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Introduction

This draft standard is based on national and international discussions. Your comments on this draft are invited and will assist in the preparation of the consequent standard.

For international standards, comments will be reviewed by the relevant UK national committee before sending the consensus UK vote and comments to the international committee, which will then decide appropriate action. If the international standard is approved, it is usual for the text to be published as a British Standard.

For national standards, comments will be reviewed by the relevant UK national committee and the resulting standards published as a British Standard.

UK Vote

Please indicate whether you consider the UK should submit a negative (with supporting technical reasons) or positive vote on this draft. Please indicate if you are aware of any reason why this draft standard should not be published as a British Standard.

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- All comments should be submitted online at <https://standardsdevelopment.bsigroup.com/>. You will need to register in order to comment.

Template for comments and secretariat observations

Date: xx/xx/20xx	Document: ISO/DIS xxxx
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1	2	(3)	4	5	(6)	7
MB	Clause No./ Subclause No./Annex (e.g. 3.1)	Paragraph/ Figure/Table/Note	Type of comment	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
	3.1	Definition 1	ed	Definition is ambiguous and needs clarifying.	Amend to read '...so that the mains connector to which no connection...'	
	6.4	Paragraph 2	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	

English Version

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

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

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

This draft European Standard is submitted to CEN members for second 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.

This draft European Standard was established by CEN in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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European foreword

This document (prEN 455-5:2024) 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.

EN 455-series 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 localized to the area of contact with the offending chemicals and unlike Type I allergic reactions do not show any systemic non-localized 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:

- concentration and ease of release of the chemicals;
- duration and frequency of skin contact with gloves;
- occlusive nature of the glove/skin interaction during glove use.

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 sensitization 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 sensitization or provocation of allergic responses in users.

This document specifies a method 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.

EN 455-3 specifies requirements for the evaluation of biological safety for medical gloves for single use including requirements for labelling and the disclosure of information relevant to the test methods used.

1 Scope

This document specifies a test method for the measurement of residual chemicals used in product manufacture, particularly potentially allergenic substances employed and remaining in medical gloves. It also provides information on the extraction vehicle, the method of extraction and quantitative assay of residual chemicals.

This document does not provide information on the allergenic potential, biological evaluation, or safety to the user of any product.

2 Normative references

There are no normative references in this document.

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

3.2

chemical

substance added or formed during any step of the manufacturing process, including sterilisation, or in storage which can 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.

3.3

curing agent

chemical which causes crosslinking to occur

Note 1 to entry: For glove materials, this is 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.

3.4

leachable

substance that is released from a medical device or material during its clinical use

Note 1 to entry: For many medical devices, a leachables study is not practical due to challenges with reproducing actual clinical conditions, so simulated-use extraction studies are often performed instead. See definition for simulated-use extraction.

[SOURCE: EN ISO 10993-18:2020, 3.22]

3.5

extractable

substance that is released from a medical device or material of construction when the medical device or material is extracted using laboratory extraction conditions and vehicles

[SOURCE: EN ISO 10993-18:2020, 3.16]

3.6

extraction vehicle

medium (solution or solvent) which is used to extract (or leach) a test article for the purpose of establishing the test article's extractables or leachables profile

Note 1 to entry: It is preferred that extraction vehicles be analytically expedient.

[SOURCE: EN ISO 10993-18:2020, 3.18, modified – Note 2 to entry has been changed]

3.7

simulated-use extraction

extraction using a method that simulates clinical use

Note 1 to entry: A simulated-use extraction is performed to estimate the type and amount of substances that are expected to be released from a medical device during its clinical use. A simulated-use extraction is designed to produce an extractables profile that represents the worst-case leachables profile, meaning that all leachables are also extractables and the levels of all individual extractables are at least equal to the level of all individual leachables.

[SOURCE: EN ISO 10993-18:2020, 3.35]

3.8

contact allergen

substance known or suspected to cause Type IV allergy

3.9

accelerator

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 Test methods

4.1 General

All test methods used to show conformity to this document shall be validated and documented by the laboratory. Annex F provides a rationale for the test method detailed in this document.

NOTE Sources of guidance on test method validation can be found in [4] and [5].

There is no single assay method to analyse every residual chemical, therefore no reference method can be defined. For assay methods that can be used see Table E.1 in Annex E.