



BSI Standards Publication

Medical gloves for single use

Part 5: Extractable chemical residues

National foreword

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The UK participation in its preparation was entrusted to Technical Committee CH/205/3, Medical gloves.

A list of organizations represented on this committee can be obtained on request to its committee manager.

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English Version

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

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

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European foreword

This document (EN 455-5:2025) has been prepared by Technical Committee CEN/TC 205 “Non-active medical devices”, the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by February 2026, and conflicting national standards shall be withdrawn at the latest by February 2026.

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.

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.

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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 is 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. At the time of publication of EN 455-5 the intention is that EN 455-3 will be revised to include further requirements related to EN 455-5.

Considering that this is the first version of EN 455-5, it is recognized that laboratories need several months after publication to obtain accreditation and begin offering accredited testing to this new standard.

1 Scope

This document specifies a test method for the measurement of residual chemicals used in product manufacture, particularly potentially Type IV allergenic substances employed and remaining in medical gloves. It also provides information on the extraction medium, 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 non-exhaustive 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 mediums

[SOURCE: EN ISO 10993-18:2020, 3.16, modified – “vehicles” was changed to “mediums” in the definition]

3.6

extraction 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 mediums be analytically expedient.

[SOURCE: EN ISO 10993-18:2020, 3.18, modified – “vehicle” was changed to “medium”, “medium” was deleted in the definition and Note 2 to entry was deleted.]

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 [3] and [4].

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