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STN	**Zdravotnícke rukavice na jedno použitie Časť 5: Extrahovateľné zvyšky chemických látok**	**STN EN 455-5** 63 7414

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

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 10/25

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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 European Standard was approved by CEN on 30 June 2025.

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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of an identical text or by endorsement, at the latest by February 2026, and conflicting national standards shall be withdrawn at the latest by February 2026.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.

Any feedback and questions on this document should be directed to the users’ national standards body. A complete listing of these bodies 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.