BSI Standards Publication

Medical gloves for single use

Part 3: Requirements and testing for biological evaluation

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National foreword

This British Standard is the UK implementation of EN 455-3:2023. It supersedes BS EN 455-3:2015, which will be withdrawn on 29 November 2025.

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 3: Requirements and testing for biological evaluation

Gants médicaux non réutilisables - Partie 3 : Exigences et essais pour évaluation biologique

Medizinische Handschuhe zum einmaligen Gebrauch - Teil 3: Anforderungen und Prüfung für die biologische Bewertung

This European Standard was approved by CEN on 29 October 2023.

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European foreword

This document (EN 455-3:2023) 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of an identical text or by endorsement, at the latest by May 2024, and conflicting national standards shall be withdrawn at the latest by November 2025.

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 supersedes EN 455-3:2015.

Compared to the previous edition EN 455-3:2015 the following main changes have been introduced:

a) update of Clause 3 'Terms and definitions';

b) update of Clause 4 'Requirements' especially in regard of the subclauses 'Chemicals', 'Endotoxins' and 'Labelling';

c) clarification of 5.3, NOTE 2

d) update of Clause 6 'Test report'

e) alignment of Annex ZA to the MDR;

f) complete editorial revision.

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.

The following part is under development:

— Part 5: Extractable chemical residues.

This document has been prepared under a standardization request addressed to CEN by the European Commission. The Standing Committee of the EFTA States subsequently approves these requests for its Member States.

For the relationship with EU Legislation, see informative Annex ZA, which is an integral part of this document.

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.