

Test methods for wound dressings - Aspects of absorption, moisture vapour transmission, waterproofness and extensibility

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

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English Version

Test methods for wound dressings - Aspects of absorption,
moisture vapour transmission, waterproofness and
extensibility

Méthodes d'essai pour pansements en contact avec la
plaie - Absorption, perméabilité à la vapeur d'eau,
imperméabilité à l'eau et extensibilité

Prüfverfahren für Verbandstoffe (Wundauflagen) -
Aspekte des Saugverhaltens, der
Feuchtigkeit durchdringung, Wasserdichtheit und
Anpassungsfähigkeit

This European Standard was approved by CEN on 17 April 2023.

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COMITÉ EUROPÉEN DE NORMALISATION
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European foreword

This document (EN 13726:2023) 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of an identical text or by endorsement, at the latest by March 2024, and conflicting national standards shall be withdrawn at the latest by March 2024.

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 13726-1:2002, EN 13726-2:2002, EN 13726-3:2003 and EN 13726-4:2003.

This document is a merger of the previously published individual parts of the EN 13726 standard series. Annex A has been included which outlines the rationale for the major revisions of EN 13726 parts 1–4.

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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1 Scope

This document specifies test methods for the evaluation of aspects of absorption of wound dressings, test methods for the evaluation of moisture vapour transmission rate of permeable film wound and fixation dressings, and test methods to assess waterproofness and extensibility.

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 single absorbent layer dressing

wound dressing incorporating a single type of absorbing material

EXAMPLE This could include a dressing containing a single absorbing material, or one absorbing material with a backing film and adhesive layer.

3.2 multi-absorbent layered dressing

wound dressing incorporating more than one type of absorbing material

EXAMPLE a dressing containing both a gelling fibre and foam layers

3.3 gelling fibre dressing

single absorbent layer wound dressings that 'gel' freely when in contact with physiological fluid

EXAMPLE alginates, hydrofibres and other gelling fibre dressings

3.4 foam dressing

single absorbent layer wound dressing incorporating an absorbent open cellular solid

EXAMPLE polyurethane based foams

3.5 film dressing

single component wound dressing consisting of a non-absorbing material which can also include an adhesive layer

EXAMPLE semi-permeable film materials