# SLOVENSKI STANDARD
# SIST EN 13726:2024

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**Nadomešča:**
**SIST EN 13726-1:2002**
**SIST EN 13726-1:2002/AC:2004**
**SIST EN 13726-2:2002**
**SIST EN 13726-3:2003**
**SIST EN 13726-4:2003**

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**Preskusne metode za sanitetni material za oskrbo rane - Vidiki absorpcije, prepustnosti vodne pare, vodoodpornosti ter raztegljivosti**



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

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



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

**Ta slovenski standard je istoveten z:** **EN 13726:2023**

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EUROPEAN STANDARD

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# EN 13726

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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

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

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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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of an identical text or by endorsement, at the latest by November 2023, and conflicting national standards shall be withdrawn at the latest by November 2023.

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.

According to the CEN-CENELEC Internal Regulations, the national standards organisations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

# 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

**3.6**
**super-absorbent dressing**
single absorbent layer wound dressing incorporating super absorbent polymer particles to achieve significant absorbent capacity of several times their weight in liquid

EXAMPLE a polyacrylate, that can absorb several times their weight in liquid

**3.7**
**amorphous hydrogel dressing**
semi-solid gel that contains hydrophilic polymers and water

**3.8**
**hydrocolloid dressing**
single absorbent layer gel-forming wound dressing

EXAMPLE a hydrocolloid would typically contain carboxymethyl-cellulose (CMC) as the principal gel forming absorbent combined with elastomers and applied to a carrier – commonly consisting of a sheet of polyurethane foam or film.

**3.9**
**fixation dressing**
wound dressing that is used to retain a product such as a medical device in place

EXAMPLE an intravenous catheter dressing

**3.10**
**bordered dressing**
consists of at least one absorbent layer that constitutes the wound pad, and one backing film layer larger than the wound pad forming a border usually covered by an adhesive



**3.11**
**free swell absorptive capacity**
total absorptive capacity in the presence of excess test liquid and in the absence of any applied load



Note 1 to entry: expressed in g of the complete wound dressing and g/cm$^2$ of the absorbent area for intact wound dressings

Note 2 to entry: expressed in g/cm$^2$ of the absorbent area for sectioned sheet wound dressings

Note 3 to entry: expressed in g/g of sample for rope/ribbon cavity wound dressings

**3.12**
**fluid retention capacity**
absorbed fluid retained in the wound dressing following application of load

Note 1 to entry: expressed in g of the intact wound dressing, g/cm$^2$ of the absorbent area and percentage of the fluid retained

**3.13**
**fluid absorbed**
fluid absorbed by the wound dressing

Note 1 to entry: expressed as ABS in g/cm$^2$ of the absorbent area

**3.14**
**moisture vapour loss**
fluid transpired through the wound dressing

Note 1 to entry: expressed as MVL in g/cm$^2$ of the absorbent area

**3.15**
**fluid handling capacity**
sum of the fluid absorbed (ABS) and the moisture vapour loss (MVL)

Note 1 to entry: expressed as FHC in g/cm$^2$ of the absorbent area

**3.16**
**moisture vapour transmission rate**
rate of permeability of materials to the passage of moisture vapour molecules from the skin contact side to the external atmosphere under controlled conditions of humidity and temperature

Note 1 to entry: expressed as MVTR in g/cm$^2$/24 h of the absorbent area

**3.17**
**fluid donation of a wound dressing**
ability to donate fluid to a simulated wound

**3.18**
**waterproofness**
ability to withstand a hydrostatic head of 500 mm



**3.19**
**conformability of a wound dressing**
ability to adapt to the shape and movement of the body

**3.20**
**extensibility**
force needed to stretch a dressing in one dimension to a known extension



Note 1 to entry: expressed in N/cm

**3.21**
**permanent set**
increase in length of a sample after stretching and relaxing in one direction

Note 1 to entry: expressed as a percentage (%) of the original length

**3.22**
**fully saturated**
when no further fluid can be absorbed

# 4 Requirements

When tested as described in Annex G, gelling wound dressings shall either be classified as a dispersion or non-dispersion wound dressing.

When tested as described in Annex J, waterproof wound dressings shall not show any signs of fluid penetration.

Wound dressings claiming compliance with any of Annex B, Annex E, Annex F, Annex H, Annex I and Annex K shall be tested in accordance with the methods described in the relevant Annex. Optional additional tests are presented in Annex C and Annex D.

Table 1 contains a list of suggested test methods and the corresponding list of dressings types which can be tested using that method.

**Table 1 — Indicative guide to test methods for wound dressings**

| Wound dressing | Annexes | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | B | C | D | E [a] | F | G | H | I | J [b] | K |
| Single absorbent layer dressing | x | x | x | x | | | | | x | x |
| Multi-absorbent layered dressing | x | x | x | x | | | | | x | x |
| Gelling fibre dressing | x | x | x | | | x | | | | |
| Foam dressing | x | x | x | x | | | | | x | x |
| Film dressing | | | | | | | x | x | x | x |
| Hydrocolloid sheet dressing | | | | x | | | | | x | x |
| Super absorbent dressing | x | x | x | x | | | | | x | |
| Amorphous hydrogel dressing | | | | | x | | | | | |

[a] Wound dressings shall have a liquid impermeable backing film to be tested for this method.

[b] Wound dressings should have a liquid impermeable backing film.



# 5 Test methods

The test methods in the present document are *in vitro* tests. The test results should always be evaluated with caution considering the intended use of the tested product and the clinical situation simulated by the test method.

Not all types of wound dressings are suitable to be tested to all of the Annexes in this standard. A list of possible test methods for different types of wound dressings is presented in Table 1. This is intended to be a guide for test method selection and is not comprehensive.

The pressures in Annex C and Annex D are reported in millimetres of mercury (mmHg) as this is the standard pressure unit used by industry and recognized by clinicians for wound care products such as compression garments. It is acknowledged that the SI unit of pressure is pascals (Pa) and a formula for conversion of mmHg to Pa has been included for reference below:

1 mmHg = 133 Pa (to change pressure results from mmHg to Pa multiply by 133)

Dressings shall not be modified or mechanically treated before they are tested. Cutting of the dressing where necessary is, however, allowed.

Any deviations from the test parameters listed in this standard shall be validated by the laboratory undertaking the test, and deviations noted in the test report.

# Annex A
(informative)

# Rationale for revision for EN 13726 parts 1–4

Since EN 13726 parts 1, 2, 3 and 4 were published, dressings technology has changed significantly. Test method parameters which seemed reasonable when the standard was first drafted are now causing operational difficulties for test houses, manufacturers and purchasers.

During the same period, European procurement legislation has also changed, and it is increasingly common for contracts to specify that data be provided in compliance with EN 13726. However, the technical issues now inherent in the standard mean that the usefulness of some of this data is questionable, and in fact can be misleading.

The technical issues include the following:

1. The term primary has been removed as the tests are applicable to both primary (direct contact with wound) and secondary (indirect contact with wound) dressings. An example would be film dressings, which are often used on top of an absorbent layer.

2. There is similarity between parts 1–4 of EN 13726, and therefore these have been merged into a single document. Individual tests are now presented as separate Annexes.

3. The revised document now includes the following additional tests. These methods are informative at present as inter-laboratory experiments have shown unexplained variation, especially between laboratories.

   — Fluid Retention Capacity (Annex C) – This test simulates a dressing which has absorbed and then exposed to pressure such as a patient rolling over onto the dressing e.g. sacral or thigh wound.

   — Absorption Under Compression (Annex D) – Many dressings are now designed to be used under compression bandages/hosiery, and have the ability to absorb under compression, but EN 13726 had no option to test in this manner. The test method in Annex D simulates a dressing under pressure before absorbing fluid e.g. dressings under compression bandages.

4. Some of the test methods in previous versions of the standard were being used for classes of dressings where they are inappropriate. For example, the EN 13726-1:2002, 3.2 “Free Swell Absorptive Capacity” test is being used for super-absorbent dressings. This requires sectioning of the dressings which can cause leaching of the super-absorbent from the dressing and thus lower than expected absorption results. The Free-Swell Absorption (Annex B) test in this revised document has been modified to allow the testing of intact dressings.

5. Incubation times (30 min) for Annex B and Annex D are based on previous work the UK has undertaken and a report is available online see [1] in Bibliography.

6. The dressing is now placed into the test solution obliquely (edgeways on) for testing to Annex B. Testing undertaken by the working group has shown that this minimizes the possibility of air pockets forming on the dressing surface during testing.

7. The tests in Annex B to Annex E are based on fully saturated dressings which is rarely the clinical situation. Most dressings will leak long before they are fully saturated and the dressings will be changed earlier. In addition, many dressings have a breathable backing film and will evaporate the exudate (moisture vapour loss) resulting in a partly saturated dressing during use, which is not considered in Annex B to Annex D.

8. Foams, hydrocolloids and super-absorbent wound dressings are now common in wound care, but test parameters needed to be revised to make the tests appropriate. Definitions have been added for these products.

9. When using the previous EN 13726-1:2002 Fluid Handling Capacity and EN 13726-2:2002 Moisture Vapour Transmission Rate test methods, the MVT of some new dressings was so high that they created a partial vacuum in the test chamber, distorting the dressing and causing inverse doming. This can stretch the dressing, thereby increasing the surface area of the dressing leading to significant over-estimates of the dressing's fluid handling capacity. In addition, challenge volumes are too low for some dressings, resulting in misleading results. The UK have undertaken inter-laboratory investigations which show that this issue can be resolved through the use of a plate including a small vent hole (0,25 mm diameter) which allows pressure to equalize, thus stopping dressing doming. A copy of this report is available online see [2] in Bibliography.

10. The test cylinder used in Fluid Handling Capacity (Annex E) and MVTR (Annex H and I) is listed separately in Annex M. The design of the test cylinder has been updated to include the use of a vented lid where appropriate (Annex E and Annex I testing), which resolves the issue discussed in step A.9 above, and also the use of bolts which are tightened to 2 Nm torque to provide more consistency in sealing the assembly.

11. A minimum air gap of 2 cm between the surface of the samples and the surface of the incubator shelf has been standardized for Fluid Handling Capacity (Annex E) and MVTR (Annex H and I) testing. Testing performed by the working group showed that this distance had no significant effect on moisture vapour component and ensured unobstructed airflow across the surface of the samples.

12. A modification of the test cylinder to accommodate testing multi absorbent layered dressings that are prone to leakage using a gasket is detailed in the informative Annex N. This is based on round robin experiments performed by the working group.

13. The test solution (Solution A) used for Free Swell Absorption (Annex B), Fluid Retention Capacity (Annex C), Absorption Under Compression (Annex D), Fluid Handling Capacity (Annex E), Fluid Donation (Annex F), Dispersion Characteristics (Annex G), and MVTR testing (Annex H and Annex I) is specified separately in Annex L. The working group recognize that laboratories may wish to use other test fluids that simulate wound exudate. If using alternative test fluids, then this is noted as a deviation to the method and include the rationale for selection of that particular fluid. However, in cases of dispute the reference Test Solution A shall be used.

14. The incubation time for Fluid Handling Capacity (Annex E) has been standardized to 24 h with the option to perform the test over longer periods if needed. The requirement to allow the cylinders to acclimatize before weighing has been removed as recent work has shown that the difference is negligible. A copy of this report is available online see [3] in Bibliography.