SLOVENSKI STANDARD
SIST EN 13726-3:2003

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Neaktivni medicinski pripomoļ ki ï Preskusne metode za sanitetni material za primarno oskrbo rane - 3. del: Odpornost proti vodi

Non-active medical devices - Test methods for primary wound dressings - Part 3: Waterproofness

Nichtaktive Medizinprodukte - Prüverfahren für primäre Verbandstoffe (Wundauflagen) - Teil 3: Wasserdichtheit

Dispositifs médicaux non-actifs - Méthodes d'essai pour les pansements primaires en contact avec la plaie - Partie 3: Résistance a la pénétration de l'eau

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ICS:

11.120.20	Sanitetni materiali, obveze in komprese	Wound dressings and compresses

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Non-active medical devices - Test methods for primary wound dressings - Part 3: Waterproofness

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This European Standard was approved by CEN on 21 February 2003.

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This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Management Centre has the same status as the official versions.

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Foreword

This document (EN 13726-3:2003) has been prepared by Technical Committee CEN /TC 205, "Non-active medical devices", the secretariat of which is held by BSI.

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of an identical text or by endorsement, at the latest by October 2003, and conflicting national standards shall be withdrawn at the latest by October 2003.

EN 13726 consists of the following Parts under the general title *Non-active medical devices* - *Test methods for primary wound dressings:*

Part 1: Aspects of absorbency

Part 2: Moisture vapour transmission rate of permeable film dressings

Part 3: Waterproofness

Part 4: Conformability

Part 5: Bacterial barrier properties

Part 6: Odour control

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Slovakia, Spain, Sweden, Switzerland and the United Kingdom.

Introduction

EN 13726 gives test methods and does not contain performance requirements.

EN 13726-3 describes a test method for waterproofness of primary wound dressings.

Test methods for other aspects of primary wound dressings are described in other parts of EN 13726.

1 Scope

This European Standard describes a test method for the evaluation of waterproofness of primary wound dressings when such claims are made.

2 Terms and definitions

For the purposes of this European Standard, the following terms and definitions apply:

2.1
primary wound dressing
material or combination of materials, in any shape, form or size that is intended to remain in direct contact with a wound

NOTE Primary wound dressings are used as mechanical barriers, for the absorption or transmission of exudates, to manage the micro-environment of the wound, and can enable the wound to heal by primary or secondary intent. Devices which have a metabolic, pharmacological or immunological interaction as their primary intent are excluded

2.2
waterproof(ness)
ability to withstand a hydrostatic head of 500 mm water for 300s

3 Test method for waterproofness

3.1 Test conditions

Condition the sample for at least 16 h at of (60 ± 15) % RH and a temperature of (21 ± 2) ºC and carry out the test in the same environment.

3.2 Waterproofness

3.2.1 Significance and use

The test is designed to assess whether a primary wound dressing is waterproof.

NOTE 1 This test may not be suitable for some types of primary wound dressings e.g. some hydrocolloids.

NOTE 2 This test may not be able to detect the waterproofness of some slowly hydrating primary wound dressings where hydration is not achieved during the duration of the test.

3.2.2 Equipment

3.2.2.1 Apparatus for measurement of waterproofness (see Figure 1), consisting of a cell which allows the application of a hydrostatic head of 500 mm of water for 300s to a circular area of the specimen with the surface opposite to the wound contact side towards the water. The specimen is held in a horizontal position by two rings, the lower one forming part of the cell. A screw device allows clamps to be tightened so as to prevent leakage of water or the movement of the specimen during the test. The hydrostatic head is generated by means of a vertical tube with a minimum internal diameter of 3 mm connected to the base of the cell.

NOTE To prevent leakage the ring surfaces in contact with the specimen may need to be covered by a suitable coating material such as rubber.

3.2.2.2 Distilled/ deionised water.

3.2.2.3 Standard cellulose based filter paper.

3.2.3 Procedure

3.2.3.1 The specimens shall be prepared without folding.

3.2.3.2 Fill the cell completely with purified water at (21 ± 2) ºC.

3.2.3.3 Place the specimen on the lower ring by sliding it horizontally in such a way as to avoid the inclusion of air between the surface of the water and the lower surface of the specimen.

3.2.3.4 Cover the upper surface of the specimen with a dry filter paper larger than the test area, locate the upper ring, and tighten the screw device.

3.2.3.5 Pour water into the tube until the required level above the surface of the specimen is reached.

3.2.3.6 Maintain the hydrostatic head for (300 ± 10) s.

3.2.3.7 Examine the filter paper for penetration of water through the specimen and record the result.

3.2.3.8 Repeat 3.2.3.2 to 3.2.3.7 on a further two specimens.

3.2.4 Calculation of results

Examine the filter paper for penetration of water through the specimen and record the results. If water penetration has occurred on any of the three specimens the sample has failed the test.

3.2.5 Test report

The report shall include at least the following information:

a) type of dressing, including lot number;

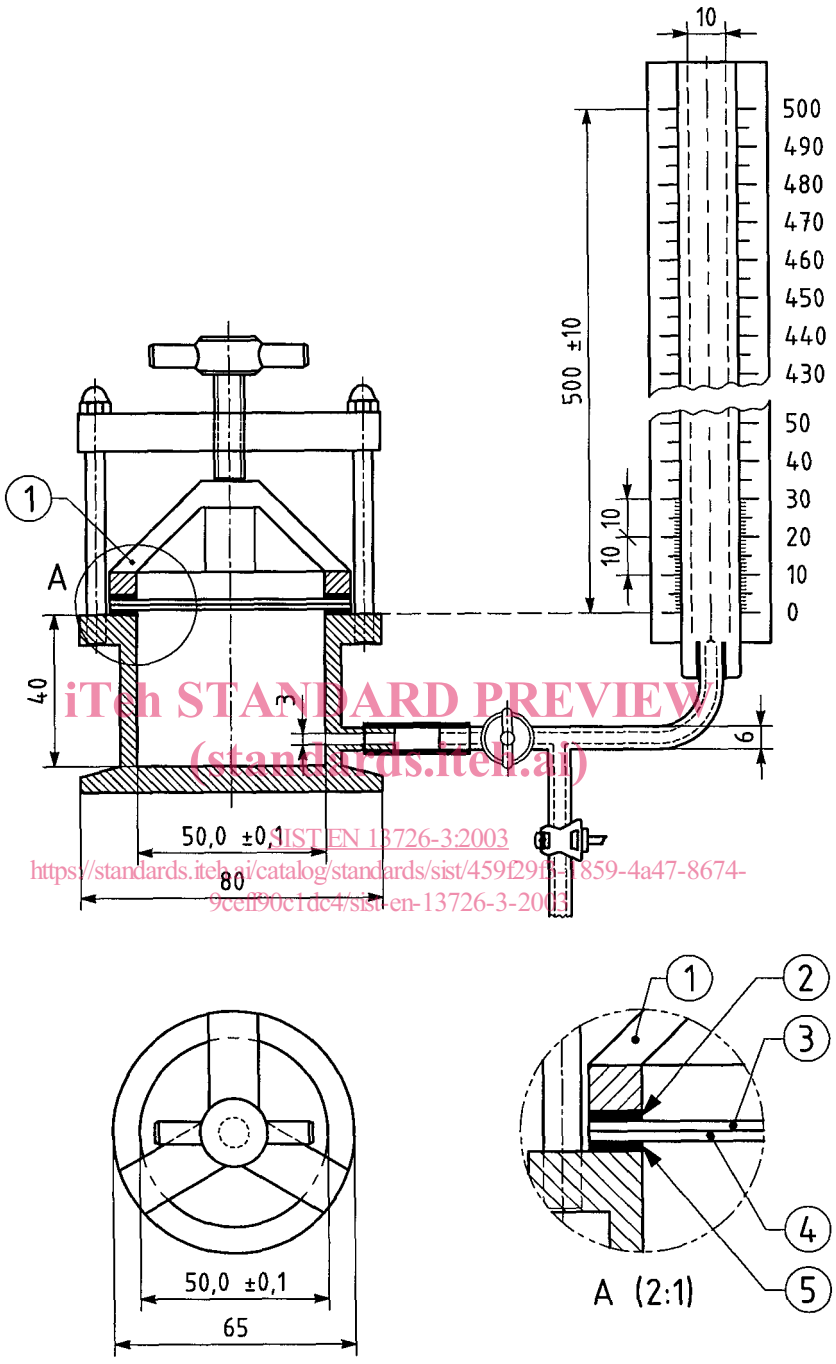
b) any deviations from the test method;

c) whether the sample has passed or failed the test;

d) date of test;

e) identity of the person(s) who carried out the test.

Dimensions in millimetres



Key
1 Pressure
2 Gasket
3 Filter paper
4 Sample
5 Gasket

Figure 1 — Apparatus for measurement of waterproofness