

Non-active medical devices — Test methods for primary wound dressings —

Part 3: Waterproofness

The European Standard EN 13726-3:2003 has the status of a
British Standard

ICS 11.120.20

National foreword

This British Standard is the official English language version of EN 13726-3:2003.

The UK participation in its preparation was entrusted by Technical Committee CH/205, Non-active medical devices, to Subcommittee CH/205/1, Medical textiles, which has the responsibility to:

- aid enquirers to understand the text;
- present to the responsible international/European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;
- monitor related international and European developments and promulgate them in the UK.

A list of organizations represented on this subcommittee can be obtained on request to its secretary.

Cross-references

The British Standards which implement international or European publications referred to in this document may be found in the *BSI Catalogue* under the section entitled "International Standards Correspondence Index", or by using the "Search" facility of the *BSI Electronic Catalogue* or of British Standards Online.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

Compliance with a British Standard does not of itself confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 13 May 2003

Summary of pages

This document comprises a front cover, an inside front cover, the EN title page, pages 2 to 6, an inside back cover and a back cover.

The BSI copyright date displayed in this document indicates when the document was last issued.

Amendments issued since publication

Amd. No.	Date	Comments

© BSI 13 May 2003

ISBN 0 580 41799 9

ICS 11.120.20

English version

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

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

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

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

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Management Centre or to any CEN member.

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.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Slovakia, Spain, Sweden, Switzerland and United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITE EUROPEEN DE NORMALISATION
EUROPAISCHES KOMITEE FÜR NORMUNG

Management Centre: rue de Stassart, 36 B-1050 Brussels

Contents

page

Foreword.....	3
Introduction.....	4
1 Scope.....	4
2 Terms and definitions.....	4
3 Test method for waterproofness.....	4
3.1 Test conditions.....	4
3.2 Waterproofness.....	4
3.2.1 Significance and use.....	4
3.2.2 Equipment.....	5
3.2.3 Procedure.....	5
3.2.4 Calculation of results.....	5
3.2.5 Test report.....	5

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 $(60 \pm 15) \% \text{ RH}$ and a temperature of $(21 \pm 2) ^\circ\text{C}$ 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 $(21 \pm 2) ^\circ\text{C}$.

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.

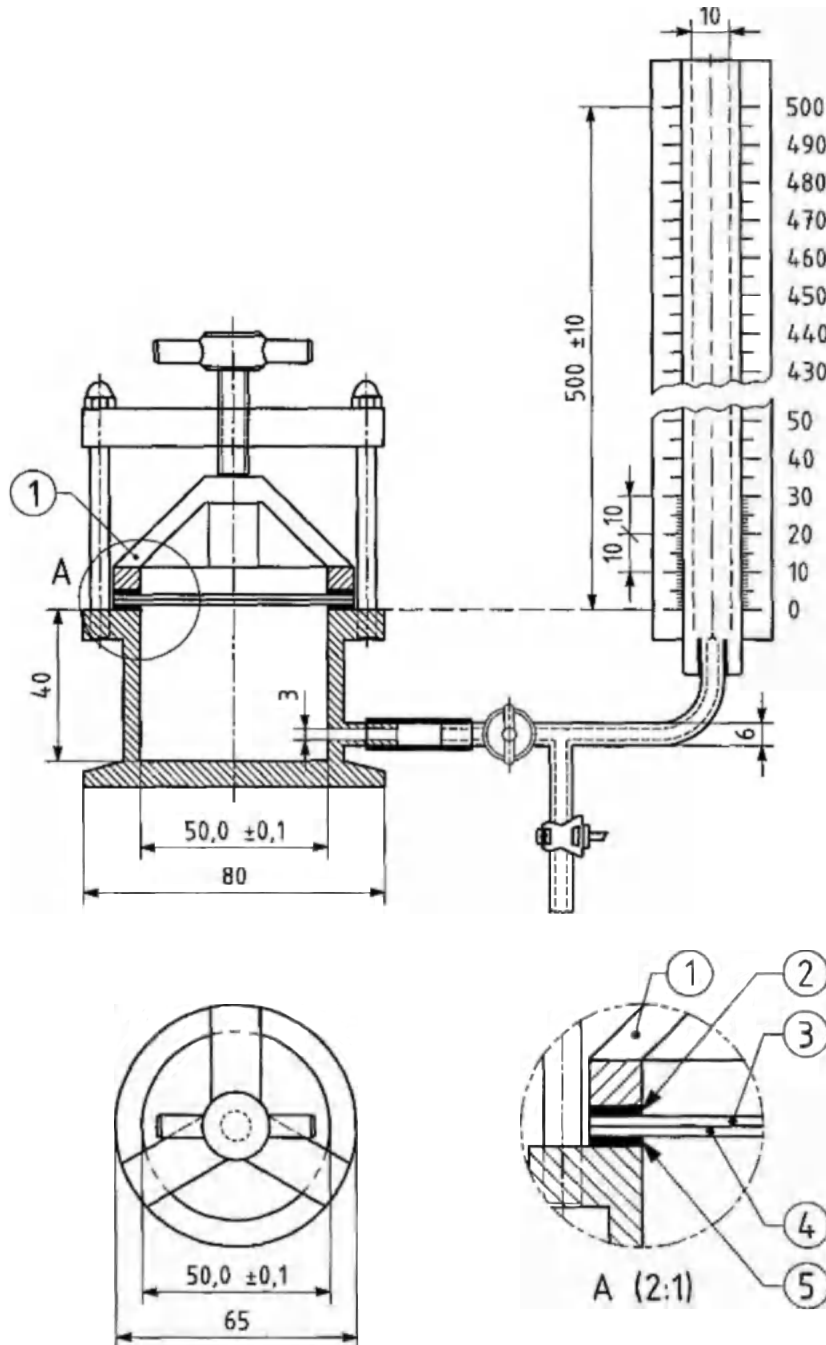
3.2.4 Calculation of results

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.



Key

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

Figure 1 — Apparatus for measurement of waterproofness

BSI — British Standards Institution

BSI is the independent national body responsible for preparing British Standards. It presents the UK view on standards in Europe and at the international level. It is incorporated by Royal Charter.

Revisions

British Standards are updated by amendment or revision. Users of British Standards should make sure that they possess the latest amendments or editions.

It is the constant aim of BSI to improve the quality of our products and services. We would be grateful if anyone finding an inaccuracy or ambiguity while using this British Standard would inform the Secretary of the technical committee responsible, the identity of which can be found on the inside front cover.
Tel: +44 (0)20 8996 9000. Fax: +44 (0)20 8996 7400.

BSI offers members an individual updating service called PLUS which ensures that subscribers automatically receive the latest editions of standards.

Buying standards

Orders for all BSI, international and foreign standards publications should be addressed to Customer Services. Tel: +44 (0)20 8996 9001.

Fax: +44 (0)20 8996 7001. Email: orders@bsi-global.com. Standards are also available from the BSI website at <http://www.bsi-global.com>.

In response to orders for international standards, it is BSI policy to supply the BSI implementation of those that have been published as British Standards, unless otherwise requested.

Information on standards

BSI provides a wide range of information on national, European and international standards through its Library and its Technical Help to Exporters Service. Various BSI electronic information services are also available which give details on all its products and services. Contact the Information Centre.
Tel: +44 (0)20 8996 7111. Fax: +44 (0)20 8996 7048. Email: info@bsi-global.com.

Subscribing members of BSI are kept up to date with standards developments and receive substantial discounts on the purchase price of standards. For details of these and other benefits contact Membership Administration.
Tel: +44 (0)20 8996 7002. Fax: +44 (0)20 8996 7001.
Email: membership@bsi-global.com.

Information regarding online access to British Standards via British Standards Online can be found at <http://www.bsi-global.com/bsonline>.

Further information about BSI is available on the BSI website at <http://www.bsi-global.com>.

Copyright

Copyright subsists in all BSI publications. BSI also holds the copyright, in the UK, of the publications of the international standardization bodies. Except as permitted under the Copyright, Designs and Patents Act 1988 no extract may be reproduced, stored in a retrieval system or transmitted in any form or by any means — electronic, photocopying, recording or otherwise — without prior written permission from BSI.

This does not preclude the free use, in the course of implementing the standard, of necessary details such as symbols, and size, type or grade designations. If these details are to be used for any other purpose than implementation then the prior written permission of BSI must be obtained.

Details and advice can be obtained from the Copyright & Licensing Manager.
Tel: +44 (0)20 8996 7070. Fax: +44 (0)20 8996 7553.
Email: copyright@bsi-global.com.