

**Medicintekniska produkter – Provningsmetoder
för sårförband –**
Del 3: Vattentäthet

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

Europastandarden EN 13726-3:2003 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN 13726-3:2003.

The European Standard EN 13726-3:2003 has the status of a Swedish Standard. This document contains the official English version of EN 13726-3:2003.

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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.

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of an identical text or by endorsement, at the latest by October 2003, and conflicting national standards shall be withdrawn at the latest by October 2003.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

EN 13726-3:2003 (E)

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) °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.