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Antimicrobial wound dressings - Requirements and test method

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

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Antimicrobial wound dressings - Requirements and test method

Pansements antimicrobiens - Exigences et méthode
d'essaiAntimikrobielle Wundauflagen - Anforderungen und
Prüfverfahren

This European Standard was approved by CEN on 14 August 2023.

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EN 17854:2024 (E)**European foreword**

This document (EN 17854:2024) 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of an identical text or by endorsement, at the latest by September 2024 and conflicting national standards shall be withdrawn at the latest by September 2024.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.

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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Introduction

This document specifies a test method for establishing whether a wound dressing exerts antimicrobial activity.

This edition of the document is considered to be most suited for wound dressing types that have been tested as part of the inter-laboratory comparisons; this means those that have an active antimicrobial agent incorporated and with at least a small amount of absorbent capacity. No data has currently been generated on other types of wound dressing (e.g. film, non-absorbing, multi-layered, adhesives, bacteria-binding dressing, etc.) and therefore it is not known if this document is suitable for these wound dressing types.

The laboratory test attempts to simulate conditions of application through the use of appropriate test fluids, temperature, organisms, and exposure times, reflecting the parameters found in clinical situations. Conditions which can influence the action of wound dressings having antimicrobial properties have been included.

The conditions are intended to cover general purposes and to allow comparison between laboratories and product types.

EN 17854:2024 (E)**1 Scope**

This document specifies minimum requirements and a test method for the antimicrobial (microbicidal or microbistatic) activity of wound dressings. It applies to all wound dressings that specifically claim antimicrobial activity according to this document.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN 12353, *Chemical disinfectants and antiseptics - Preservation of test organisms used for the determination of bactericidal (including Legionella), mycobactericidal, sporicidal, fungicidal and virucidal (including bacteriophages) activity*

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