SLOVENSKI STANDARD
SIST EN 17854:2024

01-junij-2024

Protimikrobni sanitetni material - Zahteve in preskusne metode

Antimicrobial wound dressings - Requirements and test method

Antimikrobielle Wundauflagen - Anforderungen und Prüfverfahren

Pansements antimicrobiens - Exigences et méthode d'essai

Ta slovenski standard je istoveten z: EN 17854:2024

ICS:

11.120.20	Sanitetni materiali, obveze in komprese	Wound dressings and compresses

SIST EN 17854:2024 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 17854

March 2024

ICS 11.120.20

English Version

Antimicrobial wound dressings - Requirements and test method

Pansements antimicrobiens - Exigences et méthode d'essai

Antimikrobielle Wundauflagen - Anforderungen und Prüfverfahren

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

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 CEN-CENELEC 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 CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of 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 United Kingdom.

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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Ref. No. EN 17854:2024 E

Contents

Page

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of an identical text or by endorsement, at the latest by September 2024 and conflicting national standards shall be withdrawn at the latest by September 2024.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.

According to the CEN-CENELEC Internal Regulations, the national standards organizations 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.

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.

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*

3 Terms, definitions, symbols and abbreviated terms

3.1 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:

— IEC Electropedia: available at https://www.electropedia.org/

— ISO Online browsing platform: available at https://www.iso.org/obp/

3.1.1
antimicrobial wound dressing
wound dressing which can be shown to exert microbicidal or microbistatic properties

3.1.2
antimicrobial activity
A
capability of a wound dressing to either inhibit the growth or produce a reduction in the number of viable cells of relevant test organisms under specified conditions, including viable bacterial cells and/or viable vegetative yeast cells

3.1.3
dressing sample
piece of either the negative control dressing or test dressing that has been cut to the size required in this document and used during testing

3.1.4
microbicidal
capability of the wound dressing to produce at least a 3-log reduction in the number of viable cells from the test organisms when tested under the conditions in Clause 5

3.1.5
microbistatic
capability of the wound dressing to produce at least a 0-log reduction in the number of viable cells from the test organisms when tested under the conditions in Clause 5

3.1.6
negative control dressing
wound dressing which is the same as the dressing to be tested but without the antimicrobial treatment

Note 1 to entry: If no similar wound dressing without the antimicrobial treatment is available, then a sterile gauze swab shall be used.

3.1.7
neutralizer
chemical formulation to stop the antimicrobial effect of antimicrobial agents

3.1.8
plate count method
method in which the number of viable microorganisms present after incubation is calculated by counting the number of CFU

3.1.9
plate factor
PF
factor used in CFU calculations which accounts for the volume of suspensions plated out onto agar plates

Note 1 to entry: This factor differs depending on choice of pour plates or spread plates.

3.1.10
saturation volume
SV
maximum volume of fluid absorbed by the dressing sample when tested according to the method in 5.5 of this document

3.1.11
simulated wound fluid
SWF
test medium intended to simulate wound exudate, for suspension of test organisms prior to exposure to the dressing sample

3.1.12
test dressing
antimicrobial wound dressing which is tested to assess its antimicrobial activity

3.1.13
working volume
WV
volume of SWF added to the test or negative control dressing during the test, determined as 80 % of the saturation volume

3.2 Symbols and abbreviated terms

For the purposes of this document, the following symbols and abbreviated terms apply.

A	Antimicrobial activity
CFU	Colony forming units
C_0	Viable counts per negative control dressing at T = 0 h
C_{24}	Viable counts per negative control dressing at T = 24 h
C_C	Viable counts of *INOC C*
C_s	Viable counts per dressing sample (CFU / sample) used to calculate *INOC* C (in Table 5)
C_T	Viable counts per dressing sample (C_0, C_{24}, or T_{24})
C_V	Viable counts per ml
DF	Dilution factor
h	Hour
INITIAL STOCK	Microbial suspension in MRD harvested from agar sub-culture
INOC C	Inoculum for negative control dressing (prepared from STOCK B and calculated volume of uninoculated SWF equating to WV_C – 0,5 ml)
INOC T	Inoculum for test dressing (prepared from *STOCK B* and calculated volume of uninoculated SWF equating to WV_T – 0,5 ml)
LOD	Limit of detection
log C_0	is the average logarithmic (log) value for the number of organisms obtained from three samples of negative control dressing immediately after inoculation
log T_{24}	is the average log value for the number of organisms obtained from three samples of test dressing after incubation for 24 h
min	Minutes
N	Average number of CFU on P_1 and P_2
N_0	Undiluted test suspension
NE	Neutralization effectiveness (%)
N_{EFF}	Average Neutralizer efficacy in neutralization validation (CFU/ml)
NT	Neutralization toxicity (%)
N_{TOX}	Average Neutralizer toxicity in neutralization validation (CFU/ml)
N_{VIAB}	Average Test organism viability in neutralization validation (CFU/ml)
P_1	The number of organisms on plate 1 of duplicate agar plates (CFU)
P_2	The number of organisms on plate 2 of duplicate agar plates (CFU)

PF	Plate factor (3.1.9)
s	Second
STOCK A	Microbial suspension of *INITIAL STOCK* diluted in MRD to contain 3 × 10^8 CFU/ml to 1 × 10^9 CFU/ml, used to prepare *STOCK B* and *STOCK N*
STOCK B	Microbial suspension of *STOCK A* diluted in SWF to contain 3 × 10^6 CFU/ml to 1 × 10^7 CFU/ml
STOCK N	Microbial suspension of *STOCK A* diluted in MRD to contain 1,5 × 10^3 CFU/ml to 5,0 × 10^3 CFU/ml, used in Neutralization Validation when using 1 ml pour plates
SV	Saturation volume
SV_A	Average saturation volume of three replicates (g)
SV_{HIGH}	Highest percentage saturation volume of three replicates (%)
SV_{LOW}	Lowest percentage saturation volume of three replicates (%)
SV_{MAX}	Highest measured saturation volume of three replicates (g)
SV_{MIN}	Lowest measured saturation volume of three replicates (g)
SV_{SPREAD}	Percentage spread for the three replicates (%)
T_{24}	Viable counts per test dressing at T = 24 h
V_N	Neutralizer Volume
V_S	Volume sampled from the paddle blender bag when preparing serial decimal dilutions in 5.8.2.4 (ml)
V_T	Test volume = Neutralizer volume (V_N) + Working Volume (WV_T or WV_c) (ml)
W_0	Average dressing sample mass at T = 0 h (g)
W_{Te}	The average fully saturated dressing sample mass (g), as determined when the mass does not change between two time points by more than 5 %
W_{Tv}	Dressing sample mass following saturation in SWF at each time point as applicable (g)
WV	Working volume (3.1.13), the volume of SWF added to dressing sample during the test, determined as 80 % of the saturation volume (ml)
WV_C	Working volume (*WV*) added to the negative control dressing (ml)
WV_T	Working volume (*WV*) added to the test dressing (ml)

4 Requirements

4.1 Documentation and training

Laboratories performing the test in this document should be operating under an appropriate quality management system (such as EN ISO 13485 [1], EN ISO/IEC 17025 [2] or similar). This ensures that suitable records are retained by the test laboratory to allow full traceability of all raw data contributing to the results in the test report (5.9) and competence in microbiological testing has been established.

4.2 Microbicidal dressings

When tested using the test method described in this document, antimicrobial wound dressings shall demonstrate an antimicrobial activity of at least a 3-log reduction in activity in a valid test (5.8.5) at the mandatory exposure time of 24 h (T = 24 h) and against all three test organisms (5.3.1).

NOTE 1 Log values in the text and formulae in this document refer to $\log_{10}$.

NOTE 2 Rationale for microbicidal requirements is given in Annex D.

4.3 Microbistatic dressings

When tested using the test method described in this document, microbistatic wound dressings shall demonstrate an antimicrobial activity that prevents further growth of the initial inoculum in a valid test (5.8.5) at the mandatory exposure time of 24 h (T = 24 h) and against all three test organisms (5.3.1). This means at least a 0-log reduction is obtained, which represents no increase in test organism numbers at the mandatory exposure time of 24 h (T = 24 h) against all three test organisms (5.3.1).

4.4 Performance table

Table 1 shows the performance requirements for antimicrobial wound dressings to be classified as microbicidal or microbistatic.

Table 1 — Performance requirements for antimicrobial wound dressings

Microbicidal	Microbistatic
$A \geq 3{,}0$ against all three test organisms	$A \geq 0{,}0$ against all three test organisms
A = Antimicrobial activity (5.8.3.5)	

If a test dressing does not meet either a microbicidal or microbistatic requirement then it is non-antimicrobial according to this document.

The test report (5.9) shall be supplied where claims of compliance with this document are made.

If a manufacturer makes a claim for antimicrobial activity for exposure times in addition to the mandatory exposure time of 24 h (T = 24 h) then those additional time points may be tested using this document. The viability of the test organism of the negative control dressing shall be validated for the additional time points. The additional validation data and the test results shall be included in the test report (5.9) and made available on request.

The test method in this document may be used with additional test organisms, including moulds, provided that appropriate neutralization validation has been performed. If the results using such additional test organisms are made publicly available, then the neutralization validation shall be made available on request.

NOTE Example tables are given in Annex G.

5 Test method

5.1 Principle

A test suspension of bacteria or yeast in a solution of simulated wound fluid is inoculated into a sample of a wound dressing (test and negative control dressing). The volume of test suspension added is determined by calculating the saturation volume of the dressing sample prior to inoculation. The dressing samples are maintained at a specified temperature for a specified exposure time, then transferred to a previously validated neutralization medium so that the action of the antimicrobial agent is neutralized.