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Interested committees:

Title: Draft BS EN 14885 Chemical disinfectants and antiseptics - Application of European Standards for chemical disinfectants and antiseptics.

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Introduction

This draft standard is based on national and international discussions. Your comments on this draft are invited and will assist in the preparation of the consequent standard.

For international standards, comments will be reviewed by the relevant UK national committee before sending the consensus UK vote and comments to the international committee, which will then decide appropriate action. If the international standard is approved, it is usual for the text to be published as a British Standard.

For national standards, comments will be reviewed by the relevant UK national committee and the resulting standards published as a British Standard.

UK Vote

Please indicate whether you consider the UK should submit a negative (with supporting technical reasons) or positive vote on this draft. Please indicate if you are aware of any reason why this draft standard should not be published as a British Standard.

Submission of Comments

- **Annotated drafts are not acceptable and will be rejected.**
- All comments should be submitted online at <https://standardsdevelopment.bsigroup.com/>. You will need to register in order to comment.

Template for comments and secretariat observations

Date: xx/xx/20xx	Document: ISO/DIS xxxx
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1	2	(3)	4	5	(6)	7
MB	Clause No./ Subclause No./Annex (e.g. 3.1)	Paragraph/ Figure/Table/Note	Type of comment	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
	3.1	Definition 1	ed	Definition is ambiguous and needs clarifying.	Amend to read '...so that the mains connector to which no connection...'	
	6.4	Paragraph 2	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	

English Version

Chemical disinfectants and antiseptics - Application of European Standards for chemical disinfectants and antiseptics

Antiseptiques et désinfectants chimiques - Application
des Normes européennes sur les antiseptiques et
désinfectants chimiques

Chemische Desinfektionsmittel und Antiseptika -
Anwendung Europäischer Normen für chemische
Desinfektionsmittel und Antiseptika

This draft European Standard is submitted to CEN members for enquiry. It has been drawn up by the Technical Committee CEN/TC 216.

If this draft becomes a European Standard, 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.

This draft European Standard was established by CEN 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.

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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

Warning : This document is not a European Standard. It is distributed for review and comments. It is subject to change without notice and shall not be referred to as a European Standard.



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

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European foreword

This document (prEN 14885:2025) has been prepared by Technical Committee CEN/TC 216 “Chemical disinfectants and antiseptics”, the secretariat of which is held by AFNOR.

This document is currently submitted to the CEN-Enquiry.

This document will supersede EN 14885:2022.

EN 14885:2022 was revised to update the information on existing standards, to include standards published since 2023 and to give more details how to use the standards for making claims. CEN/TC 216 has prepared a series of standards on chemical disinfectants and antiseptics specifying requirements and test methods. The purpose of this document is to specify the relationship of the various standards to one another and to claims and use recommendations.

To allow for different requirements in different areas of application, separate tests and pass criteria have been or will be prepared for each of the following three areas of application: medical, veterinary, and a group comprising food, industrial, domestic and institutional areas.

This document only refers to test methods which are currently included in the work programme of CEN/TC 216 and which are described in Clause 2. It is likely that additional standards which relate to specific situations will be produced at a later time.

This document was revised to adapt it to the latest state of CEN/TC 216, to correct errors and ambiguities. The following is a list of significant changes since the last edition:

- Harmonization of the standard: introduction changed accordingly and clarification was added with the scope that medical devices are encompassed by the standards of WG 1;
- Normative references (2) updated, the standards revised after the last revision of EN 14885 are signposted;
- Definition for biocidal products added;
- Addition of testing in compliance with EN ISO/IEC 17025 (new 6.2);
- Further aspects for phase 3 tests added;
- New Annex G “Translation of definitions (claims)”;
- New Annex ZA Relationship between this European standard and the General Safety and Performance Requirements of Regulation (EU) 2017/745 aimed to be covered”

The changes mentioned above have no impact on the use of test results obtained with reference to the former version of EN 14885 if a standard has not been revised in the meantime. Those results are still valid. If there is a new edition in Clause 2 cited (standard revised) refer to the information in Clause 8.

This document has been prepared under a standardization request addressed to CEN by the European Commission. The Standing Committee of the EFTA States subsequently approves these requests for its Member States.

For the relationship with EU Legislation, see informative Annex ZA, which is an integral part of this document

Introduction

This document specifies the laboratory methods to be used for testing the activity of products, i.e. chemical disinfectants (including those considered as medical devices) and antiseptics in order to support claims that they have specific properties appropriate to their intended application. These laboratory methods may also be used for active substances and products under development. This document is not intended to represent disinfection policy guidelines, i.e. guidelines for choosing and assessing the suitability of products for particular situations.

The CEN standards relate to only a limited range of microbial species. These have been chosen as representative species taking into account their relative resistance and their relevance to practical use. The handling properties and the microbiological safety have also been considered in choosing the test organisms.

The test methods in this document are based on the current scientific state of the art. It is recognized that at the present time there is only limited knowledge regarding the relationship between the activity of products as determined by suspension as compared with surface tests, and the relevance of the results of both tests to conditions of use.

Chemical disinfectants and antiseptics need to always be used responsibly. This needs to take into account the environmental impact of inappropriate product in-use concentrations (too high or too low) and of unnecessary use.

This document is continuously updated as the standards it refers to are advanced and evolve. To simplify the update process, dated references are included in Clause 2, but not throughout the document. Users should refer to Clause 2 to identify the date of the referenced standard.

1 Scope

This document specifies the European Standards to which products have to conform in order to support the claims for microbicidal activity which are referred to in this document.

This document also specifies terms and definitions which are used in European Standards.

It is applicable to products for which activity is claimed against the following microorganisms: vegetative bacteria (including mycobacteria and *Legionella*), bacterial spores, yeasts, fungal spores and viruses (including bacteriophages).

It is intended to:

- a) enable manufacturers of products to select the appropriate standards to be used in order to provide data which support their claims for a specific product;
- b) enable users of the product to assess the information provided by the manufacturer in relation to the use for which they intend to use the product;
- c) assist regulatory authorities in assessing claims made by the manufacturer or by the person responsible for placing the product on the market.

It is applicable to products to be used in the area of human medicine, the veterinary area and in food, industrial, domestic and institutional areas.

In the area of human medicine (Working Group 1, i.e. WG 1), it is applicable to chemical disinfectants and antiseptics to be used in areas and situations where disinfection or antisepsis is medically indicated. Such indications occur in patient care

- in hospitals, in community medical facilities, dental institutions and medical laboratories for analyses and research,
- in clinics of schools, of kindergartens and of nursing homes,
- and may also occur in the workplace and in the home. It may also include services such as in laundries and kitchens supplying products directly for the patient.

Chemical disinfectants considered as medical devices are encompassed within WG 1.

In the veterinary area (WG 2) it is applicable to chemical disinfectants and antiseptics to be used in the areas of breeding, husbandry, veterinary care facilities, production, transport and disposal of animals and veterinary laboratories for analyses and research. It is not applicable to chemical disinfectants used in the food chain following death and entry to the processing industry.

In food, industrial, domestic and institutional areas (WG 3) it is applicable to chemical disinfectants and antiseptics to be used in processing, distribution and retailing of food of animal or vegetable origin. It is also applicable to products for all public areas where disinfection is not medically indicated (homes, catering, schools, nurseries, transports, hotels, offices etc.) and products used in packaging, biotechnology, laboratories (except laboratories for veterinary and medical analyses and research), pharmaceutical, cosmetic etc. industries.

This document is also applicable to active substances and products under development for which no area of application has yet been specified.

This document will be periodically updated to reflect the current published versions of each standard developed in CEN/TC 216. Independent of this update newly published standards are to be used, even if they are not yet mentioned in EN 14885.

This document does not refer to methods for testing the toxicological and ecotoxicological properties of products or active substances.

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 1040:2005, *Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of basic bactericidal activity of chemical disinfectants and antiseptics - Test method and requirements (phase 1)*

EN 1275:2005, *Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of basic fungicidal or basic yeasticidal activity of chemical disinfectants and antiseptics - Test method and requirements (phase 1)*

EN 1276:2019, *Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas - Test method and requirements (phase 2, step 1)*

EN 1499:2013, *Chemical disinfectants and antiseptics - Hygienic handwash - Test method and requirements (phase 2/step 2)*

EN 1500:2013, *Chemical disinfectants and antiseptics - Hygienic handrub - Test method and requirements (phase 2/step 2)*

EN 1650:2019, *Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas - Test method and requirements (phase 2, step 1)*

EN 1656:2019, *Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in the veterinary area - Test method and requirements (phase 2, step 1)*

EN 1657:2024, *Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity of chemical disinfectants and antiseptics used in the veterinary area - Test method and requirements (phase 2, step 1)*

EN 12353:2021, *Chemical disinfectants and antiseptics - Preservation of test organisms used for the determination of bactericidal (including Legionella), mycobactericidal, sporicidal, fungicidal and virucidal (including bacteriophages) activity*

EN 12791:2016+A1:2017, *Chemical disinfectants and antiseptics - Surgical hand disinfection - Test method and requirements (phase 2, step 2)*

EN 13610:2002, *Chemical disinfectants - Quantitative suspension test for the evaluation of virucidal activity against bacteriophages of chemical disinfectants used in food and industrial areas - Test method and requirements (phase 2, step 1)*

EN 13623:2020, *Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity against Legionella of chemical disinfectants for aqueous systems - Test method and requirements (phase 2, step 1)*

EN 13624:2021, *Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity in the medical area - Test method and requirements (phase 2, step 1)*

EN 13697:2023, *Chemical disinfectants and antiseptics - Quantitative non-porous surface test for the evaluation of bactericidal and yeasticidal and/or fungicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas without mechanical action - Test method and requirements without mechanical action (phase 2, step 2)*

EN 13704:2018, *Chemical disinfectants - Quantitative suspension test for the evaluation of sporicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas - Test method and requirements (phase 2, step 1)*

EN 13727:2012+A2:2015, *Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity in the medical area - Test method and requirements (phase 2, step 1)*

EN 14204:2025, *Chemical disinfectants and antiseptics — Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants and antiseptics used in the veterinary area — Test method and requirements (phase 2, step 1)*

EN 14347:2005, *Chemical disinfectants and antiseptics — Basic sporicidal activity — Test method and requirements (phase 1)*

EN 14348:2005, *Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants in the medical area including instrument disinfectants - Test methods and requirements (phase 2, step 1)*

EN 14349:2025, *Chemical disinfectants and antiseptics - Quantitative surface test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in the veterinary area on non-porous surfaces without mechanical action - Test method and requirements (phase 2, step 2)*

EN 14476:2025, *Chemical disinfectants and antiseptics — Quantitative suspension test for the evaluation of virucidal activity in the medical area — Test method and requirements (Phase 2/Step 1)*

EN 14561:2006, *Chemical disinfectants and antiseptics - Quantitative carrier test for the evaluation of bactericidal activity for instruments used in the medical area - Test method and requirements (phase 2, step 2)*

EN 14562:2006, *Chemical disinfectants and antiseptics - Quantitative carrier test for the evaluation of fungicidal or yeasticidal activity for instruments used in the medical area - Test method and requirements (phase 2, step 2)*

EN 14563:2008, *Chemical disinfectants and antiseptics - Quantitative carrier test for the evaluation of mycobactericidal or tuberculocidal activity of chemical disinfectants used for instruments in the medical area - Test method and requirements (phase 2, step 2)*

EN 14675:2015, *Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of virucidal activity of chemical disinfectants and antiseptics used in the veterinary area - Test method and requirements (Phase 2, step 1)*

EN 16437:2014+A1:2019, *Chemical disinfectants and antiseptics - Quantitative surface test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in veterinary area on porous surfaces without mechanical action - Test method and requirements (phase 2, step 2)*

EN 16438:2014, *Chemical disinfectants and antiseptics - Quantitative surface test for the evaluation of fungicidal or yeasticidal activity of chemical disinfectants and antiseptics used in the veterinary area on non-porous surfaces without mechanical action - Test method and requirements (phase 2, step 2)*

EN 16615:2015, *Chemical disinfectants and antiseptics - Quantitative test method for the evaluation of bactericidal and yeasticidal activity on non-porous surfaces with mechanical action employing wipes in the medical area (4-field test) - Test method and requirements (phase 2, step 2)*

EN 16616:2022+A1:2025, *Chemical disinfectants and antiseptics— Chemical-thermal textile disinfection — Test method and requirements (phase 2, step 2)*

EN 16777:2018, *Chemical disinfectants and antiseptics - Quantitative non-porous surface test without mechanical action for the evaluation of virucidal activity of chemical disinfectants used in the medical area - Test method and requirements (phase 2/step 2)*

EN 17111:2018, *Chemical disinfectants and antiseptics - Quantitative carrier test for the evaluation of virucidal activity for instruments used in the medical area - Test method and requirements (phase 2, step 2)*

EN 17122:2019+A1:2024, *Chemical disinfectants and antiseptics - Quantitative non-porous surface test for the evaluation of virucidal activity of chemical disinfectants and antiseptics used in the veterinary area - Test method and requirements - Phase2, step2*

EN 17126:2018, *Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of sporicidal activity of chemical disinfectants in the medical area - Test method and requirements (phase 2, step 1)*

EN 17272:2020, *Chemical disinfectants and antiseptics - Methods of airborne room disinfection by automated process - Determination of bactericidal, mycobactericidal, sporicidal, fungicidal, yeasticidal, virucidal and phagocidal activities*

EN 17387:2021, *Chemical disinfectants and antiseptics - Quantitative test for the evaluation of bactericidal and yeasticidal and/or fungicidal activity of chemical disinfectants in the medical area on non-porous surfaces without mechanical action - Test method and requirements (phase 2, step 2)*

EN 17422:2022, *Chemical disinfectants and antiseptics - Quantitative surface test for the evaluation of teat disinfectants used in the veterinary area - Test method and requirements (phase 2 step 2)*

EN 17430:2024, *Chemical disinfectants and antiseptics - Hygienic handrub virucidal - Test method and requirements (phase 2/step 2)*

EN 17658:2022, *Chemical disinfectants and antiseptics - Chemical textile disinfection for the domestic area - Test method and requirements (phase 2, step 2)*

EN 17846:2023, *Chemical disinfectants and antiseptics - Quantitative test method for the evaluation of sporicidal activity against Clostridioides difficile on non-porous surfaces with mechanical action employing wipes in the medical area (4-field test) - Test method and requirements (phase 2, step 2)*

3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at <http://www.electropedia.org/>
- ISO Online browsing platform: available at <https://www.iso.org/obp>

NOTE Some recommendations on the use of terminology in the areas of chemical disinfection and antisepsis are given in Annex B.

3.1 Chemical disinfectant or antiseptic procedures and product types

3.1.1

antiseptic

product – excluding antibiotics – that is used to bring about antiseptis

3.1.2

antiseptis

application of an antiseptic on living tissues causing an action on the structure or metabolism of microorganisms to a level judged to be appropriate to prevent and/or limit and/or treat an infection of those tissues

Note 1 to entry: The term microorganism encompasses bacteria (including mycobacteria and bacterial endospores), fungi (including moulds, fungal spores and yeasts), viruses (including bacteriophages), algae and oocysts (see also 3.3.13)

3.1.3

chemical disinfectant

product that is capable of chemical disinfection

3.1.4

chemical disinfection

reduction of the number of microorganisms in or on an inanimate or animate matrix, achieved by the irreversible action of a product on their structure or metabolism, to a level judged to be appropriate for a defined purpose

Note 1 to entry: The term microorganism encompasses bacteria (including mycobacteria and bacterial endospores), fungi (including moulds, fungal spores and yeasts), viruses (including bacteriophages), algae and oocysts (see also 3.3.13)

Note 2 to entry: Products for antiseptis are excluded

3.1.5

hygienic handrub

treatment of hands by rubbing a product without the addition of water, that is directed against transiently contaminating microorganisms to prevent their transmission regardless of the resident skin flora

3.1.6

hygienic handwash

treatment of hands by washing with product and water, that is directed against transiently contaminating microorganisms to prevent their transmission regardless of the resident skin flora

3.1.7**instrument disinfection**

chemical disinfection of certain instrument surfaces in the medical and veterinary areas by immersion

3.1.8**surface disinfection**

chemical disinfection of a solid surface, including those of certain medical and veterinary instruments which cannot be immersed, by the application of a product with or without mechanical action

Note 1 to entry: The application includes e.g. wiping, mopping, circulation, flooding, spraying, fogging, etc.

3.1.9**surgical handrub**

preoperative treatment of hands by rubbing a product without the addition of water, that is directed against the flora of microorganisms on hands to prevent the transmission of microorganisms into the surgical wound

3.1.10**surgical handwash**

preoperative treatment of hands by washing with product and water, that is directed against the flora of microorganisms on hands to prevent the transmission of microorganisms into the surgical wound

3.1.11**textile disinfection**

chemical disinfection of textiles through the application of a product by either immersion in a solution or by processing in a washing machine

3.2 Chemical disinfectant or antiseptic action**3.2.1****algaecidal activity**

capability of a product to reduce the quantity of algae as test organisms, specified in the corresponding standard(s), under defined conditions

3.2.2**bactericidal activity**

capability of a product to reduce the number of viable bacterial cells of relevant test organisms, specified in the corresponding standard(s), under defined conditions

3.2.3**fungicidal activity**

capability of a product to reduce the number of viable yeast cells and mould spores of relevant test organisms, specified in the corresponding standard(s), under defined conditions

3.2.4**microbicidal activity****microbiocidal activity**

capability of a product to reduce the number of relevant test organisms including viable bacterial cells and/or viable yeast cells and/or mould spores and/or viable bacterial endospores and/or infectious virus particles and/or infectious bacteriophage particles and/or algae and/or oocysts, specified in the corresponding standard(s)

Note 1 to entry: The above term is a general term, not to be used for claims according to Clause 7 c).

3.2.5

microbistatic activity

microbiostatic activity

capability of a product to inhibit the growth of relevant test organisms, including viable bacterial cells and/or viable yeast cells and/or mould spores and/or viable bacterial endospores and/or infectious virus particles and/or infectious bacteriophage particles and/or algae and/or oocysts under defined conditions

Note 1 to entry: The above term and related terms like “bacteriostatic”, “fungistatic” are used in CEN / TC 216 standards but cannot be used for claims according to the scope (Clause 1).

3.2.6

mycobactericidal activity

capability of a product to reduce the number of viable mycobacterial cells of relevant test organisms, specified in the corresponding standard(s), under defined conditions

3.2.7

oocysticidal activity

capability of a product to reduce the number of oocysts of relevant test organisms, specified in the corresponding standard(s), under defined conditions

3.2.8

phagocidal activity

capability of a product to reduce the number of infectious bacteriophage particles of relevant test organisms, specified in the corresponding standard(s), under defined conditions

3.2.9

sporicidal activity levels

different levels of sporicidal activity with various gradations against aerobic and/or anaerobic bacterial endospores

Note 1 to entry: The two different levels are: sporicidal activity (3.2.9.1), Sporicidal activity against *C. difficile* in human medicine (3.2.9.2).

3.2.9.1

sporicidal activity

capability of a product to reduce the number of viable aerobic and anaerobic bacterial endospores of relevant test organisms, specified in the corresponding standard(s), under defined conditions

3.2.9.2

sporicidal activity against *C. difficile* in human medicine

capability of a product to reduce the number of viable bacterial endospores of *C. difficile*, specified in the corresponding standard(s), under defined conditions

3.2.10

tuberculocidal activity

capability of a product to reduce the number of viable cells of relevant Mycobacteria as test organism, specified in the corresponding standard(s), under defined conditions

3.2.11**virucidal activity levels**

different levels of virucidal activity with various gradations

Note 1 to entry: The three different levels are: virucidal activity (3.2.11.1), limited spectrum virucidal activity (3.2.11.2) and virucidal activity against enveloped viruses (3.2.11.3)

3.2.11.1**virucidal activity**

capability of a product to reduce the number of infectious virus particles of relevant test organisms, specified in the corresponding standard(s), under defined conditions

Note 1 to entry: virucidal activity covers enveloped and non-enveloped viruses

3.2.11.2**limited spectrum virucidal activity**

capability of a product to reduce the number of infectious virus particles using certain non-enveloped viruses as test organisms, specified in the corresponding standard(s), under defined conditions, thus covering virucidal activity against these test organisms, and additionally defined other non-enveloped virus(es) and all enveloped viruses

3.2.11.3**virucidal activity against enveloped viruses**

capability of a product to reduce the number of infectious virus particles using relevant enveloped viruses as test organism, specified in the corresponding standard(s), thus covering activity against all enveloped viruses

3.2.12**yeasticidal activity**

capability of a product to reduce the number of viable yeast cells of relevant test organisms, specified in the corresponding standard(s), under defined conditions

3.3 General terms**3.3.1****active substance**

substance or microorganism that has an action on or against harmful organisms

[SOURCE: Biocide Product Regulation (EU) 528/2012, Article 3(1)(c)]

Note 1 to entry: In standards developed by CEN/TC 216 only chemical substances are used as active substances.

Note 2 to entry: The term “harmful organism” encompasses bacteria (including mycobacteria and bacterial endospores), fungi (including moulds, fungal spores and yeasts) and viruses (including bacteriophages), algae and oocysts.

Note 3 to entry: In standards developed by CEN/TC 216 the term “product” encompasses “active substance”.

3.3.2**additional test conditions**

test conditions in a standard that are optional and not obligatory, that may be used for further specific product claims and/or applications

Note 1 to entry: Such test conditions can be found in the same or in an additional standard.

3.3.3

biocidal product

biocidal products are used to control unwanted organisms that are harmful to human or animal health or to the environment, or that cause damage to human activities. These harmful organisms include pests (e.g. insects, rats or mice) and microorganisms (e.g. bacteria, viruses, mould)

[SOURCE: Overview (europa.eu)]

Note 1 to entry: Other definition for biocidal product:

— any substance or mixture, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action,

— any substance or mixture, generated from substances or mixtures which do not themselves fall under the first indent, to be used with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action,

A treated article that has a primary biocidal function shall be considered a biocidal product.

[SOURCE: Biocide Product Regulation (EU) 528/2012, Article 3(1)(a)]

3.3.4

contact time

time period during application of the product in a test that elapses between its first contact with the test organisms, and its neutralization

3.3.5

interfering substance

soiling

additional substances simulating the conditions of the soiling level in the test

Note 1 to entry: Two levels of soiling are used in the standards see clean conditions (3.3.5.1) and dirty conditions (3.3.5.2)

3.3.5.1

clean conditions

conditions representative of surfaces which have been cleaned satisfactorily and/or are known to contain minimal levels of organic and/or inorganic substances

Note 1 to entry: In the veterinary area, these conditions are called “low level soiling”. The term “low level soiling” has been introduced to avoid confusion in the veterinary area where the respective levels of soiling are higher.

3.3.5.2

dirty conditions

conditions representative of surfaces which have not been cleaned and are known to contain or potentially contain organic and/or inorganic substances

Note 1 to entry: In the veterinary area, these conditions are called “high level soiling”. The term “high level soiling” has been introduced to avoid confusion in the veterinary area where the respective levels of soiling are higher.

3.3.6**limiting test organism**

test organism that requires the highest concentration to give the specified decimal logarithm (lg) reduction (it is the least susceptible test organism to the product in the chosen experimental conditions)

3.3.7**medical device**

any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
- investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
- providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,

and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means

The following products shall also be deemed to be medical devices:

- devices for the control or support of conception;
- products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point

[SOURCE: REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC]

Note 1 to entry: In standards developed by CEN/TC 216 only products used to disinfect medical devices are considered as medical devices

3.3.8**neutralization**

process that suppresses the residual microbicidal activity of a product or active substance within a specific test but does not inactivate or inhibit the test organism using neutralizer and/or dilution (e.g. membrane filtration)

3.3.9**neutralizer**

chemical agent or formulation that is used for neutralization

3.3.10

product

formulation used as a chemical disinfectant or antiseptic

Note 1 to entry: A ready-to-use product is a product used undiluted.

Note 2 to entry: The term “product” encompasses “active substance(s)”

3.3.11

product claim

any claim derived from results of one or more test(s) (3.3.12)

3.3.12

test

technical operation that consists of the determination of one or more characteristics or performance of a given product or process according to a specified procedure based on the requirements for a specific intended use or application

[SOURCE: EN ISO 16484-2:2004-08, modified deleted “material, equipment, organism, physical phenomenon and service” and added in the end “based on the requirements for a specific intended use or application” and EN ISO 9000:2015-11, modified replaced “determination (311.1) according to requirements (3.6.4) for” by “technical operation that consists of the determination of one or more characteristics or performance of a given product or process according to a specified procedure based on the requirements for”]

3.3.13

test organism

strain of a microorganism selected for testing a product within a standardized test

Note 1 to entry: For the purpose of this document, the term microorganism includes vegetative bacteria, bacterial spores, yeasts, mould spores and viruses (including bacteriophages), algae and oocysts.

4 Procedures for claiming activity

4.1 Category of tests

The tests are categorized on a modular basis as follows:

- **Phase 1 tests** are quantitative suspension tests to establish that a product under development has bactericidal, fungicidal, yeasticidal or sporicidal activity without regard to specific areas of application. Phase 1 tests cannot be used for any product claim.
- **Phase 2** comprises two steps:
 - a) **Phase 2, step 1 tests** are quantitative suspension tests to establish that a product has bactericidal, fungicidal, yeasticidal, mycobactericidal, tuberculocidal, sporicidal, virucidal, phagocidal, algacidal or oocysticidal activity under simulated practical conditions appropriate to its intended use;
 - b) **Phase 2, step 2 tests** are quantitative laboratory tests to establish that a product has bactericidal, fungicidal, yeasticidal, mycobactericidal, tuberculocidal, sporicidal, virucidal or phagocidal, algacidal or oocysticidal activity when applied to a surface or skin under simulated practical conditions (e.g. surface, instrument, laundry, handwash and handrub tests);

- **Phase 3 tests** are field tests under practical conditions. Applicable methodologies for this type of test are not yet available, but could be developed in the future. Guidance on the design of phase 3 tests and the use of data from phase 3 tests is provided in Annex D.

NOTE In the following phase 2, step 1 is mostly shortened to “2,1” or “2/1” and phase 2, step 2 to “2,2” or “2/2”.

Phase 2, step 1 tests prove the irreversible inactivation of microorganisms. This test design provides relevant information about the activity of the product against microorganisms in suspension. Desiccated microorganisms can be stressed and can pose different challenges.

Phase 2, step 2 tests provide information about the activity against desiccated microorganisms on inanimate surfaces or on living tissues or against non-desiccated microorganisms on living tissues.

Tests shall be carried out under the minimum requirements/obligatory conditions as specified in the standards. According to the claimed use of the product, tests under additional conditions (test organisms, temperature, contact time and interfering substances) shall be carried out as specified in the standard.

Phase 2, step 1 and phase 2, step 2 tests are generally needed in combination to support efficacy claims for chemical disinfectants or antiseptics. Only in exceptional cases deviation from this principle is allowed (see relevant applications below and Annex C). Both results shall be taken into account in determination of the label claim.

4.2 General

4.2.1 In order to determine that an active substance has microbicidal properties, it can be tested in accordance with and shall conform to the relevant test conditions and requirements of the European phase 1 standards (EN 1040, EN 1275, EN 14347). For the differentiation of active and non-active substances in a product see Annex A.

4.2.2 For the medical area see 4.3, for the veterinary area see 4.4, for the food, industrial, domestic and institutional areas see 4.5. The standards specified in 4.3, 4.4 or 4.5 may be used to support product claims of activity/conformity to this European Standard on the basis of criteria specified in those standards (minimum requirements, obligatory and/or specified additional conditions).

4.2.3 When recommendations for use are made based on the standards referenced in EN 14885 these shall be supported by test results relevant for this recommendation, e.g. a result for 30 min contact time does not allow a claim for 10 min (but a result for 10 min allows a claim for 30 min if the same product concentration is recommended for use). It is not possible to extend or shorten the time for use beyond the limits (i.e. the minimum and maximum *additional* contact times in the medical, veterinary, food, industrial, domestic and institutional areas) specified in standards referred to in EN 14885 to claim conformity to the standard (see also 4.2.5.3).

4.2.4 The product marketed shall be equivalent to the one tested. Equivalent means that it contains the same active substances in the same quantity. If non-active substances have been changed in the formulation it has to be demonstrated by theoretical evaluation and/or appropriate experimentation that this change has no impact on the product's activity. The method(s) to establish that the changes have no impact on the product's activity shall be chosen taking into account the efficacy test(s) performed to support the claim of the original product and the nature of the change and its potential influence on the product's characteristics including the claim.

4.2.5 Where there is no appropriate standard for an application within a specific area, a standard from another area may be recommended for use. If later on an appropriate standard is published, this new standard shall be used. Special cases:

4.2.5.1 Where in EN 14885 no standard exists for a specific activity in an area (e.g. medical), a standard from another area (e.g. veterinary) may be used and test conditions modified for relevance to the area of application to match the specific application. In certain cases it can be necessary or recommendable to modify even the test organism(s) to match the requirements of the area. These choices shall be scientifically justified taking into account the field of application and the intended use of the product. In the test report the European Standard shall be referenced as modified; details of and the reasons for the modification shall be reported and highlighted. Conformity to the standard used shall not be claimed, but it should be stated that the product was tested in accordance with the principles of the standard.

4.2.5.2 Where in EN 14885 there is no intention to develop a test for specific product activity, the methodology in a standard specified in EN 14885 may be used and test conditions modified to match the required activity. These choices shall be scientifically justified taking into account the field of application and the intended use of the product. In the test report the European Standard shall be referenced as modified; details of and the reasons for the modification shall be reported and highlighted. Conformity to the standard used shall not be claimed, but it should be stated that the product was tested in accordance with the principles of the standard.

4.2.5.3 Where in EN 14885 no standard exists that specifies the use conditions for a specific product activity in an area (e.g. activity at a temperature or contact time not specified in the minimum requirements/obligatory or additional test conditions), a standard may be used with the relevant test condition modified for relevance to the area of application. These choices shall be scientifically justified taking into account the field of application and the intended use of the product. In the test report the European Standard shall be referenced as modified; details of and the reasons for the modification shall be reported and highlighted. Conformity to the standard used shall not be claimed, but it should be stated that the product was tested in accordance with the principles of the standard.

4.2.6 All test organisms shall be preserved and kept according to EN 12353 taking into account the specific instructions in the standard used. If additional test organisms are used the principles laid down in EN 12353 and in the standard used shall be followed as far as it is feasible and sensible. Deviations from these principles shall be scientifically justified.

4.2.7 Chemo-thermal disinfection processes are relevant in several application areas. Elevated temperatures can for example help to reduce the amount of chemicals necessary to achieve the desired goal. While for the bactericidal and virucidal efficacy spectrum relevant specific thermo-resistant test organisms have been defined for test temperatures > 40 °C and some application areas, this has not yet been achieved for other efficacy spectra and application areas. It can, however, be desirable to provide data on e.g. yeasticidal, fungicidal and/or mycobactericidal effect of chemo-thermal disinfection. Due to the limited temperature resistance of these test organisms this can lead to invalid controls of experimental conditions (control A/water control in some tests). Such tests can deliver appropriate e.g. yeasticidal, fungicidal and/or mycobactericidal results under chemo-thermal conditions. In such cases control A and/or water control shall be run in parallel at application temperature and at 20 °C. If control A and/or water control at 20 °C demonstrates the validity of the test and the efficacy at elevated temperatures is shown, the product may be considered active.

By implementing the additional control A (and water control, if applicable) at 20 °C the standard used shall be regarded validated for any temperature below the temperatures that are known to bring about mere thermal disinfection for the chosen contact time.

The same approach may also be chosen, if bactericidal and virucidal tests are conducted at temperatures > 60 °C. In these instances, control A (and water control, if applicable) shall be performed at 60 °C for the relevant thermo-resistant test organisms (instead of 20 °C) in addition to the application temperature.

4.2.8 All phase 2, step 1 and most of phase 2, step 2 standards developed by CEN/TC 216 require that a product shall be tested at a minimum of three different concentrations to include at least one concentration in the active range and one concentration in the non-active range. For environmental, occupational health and economic reasons, products at their use concentration should not contain more active substances than necessary (see Annex E for guidance to test meaningful concentrations).

4.2.9 All standards developed by CEN/TC 216 have to be conducted in accordance with all applicable European, national and local safety guidelines.

4.2.10 The **lg reduction** is usually expressed as a decimal logarithm (lg) with 3 significant figures (two figures after the comma). If the last digit is less than 5, the preceding digit is not changed; if the last digit is 5 or more, the preceding digit is increased by one unit, e.g. 5,148 lg is represented as 5,15 lg; 5,143 is represented as 5,14. If a specific standard stipulates an alternative rule for the figure presentation, the rule within the specific standard shall be used.

EXAMPLE: Currently EN 13704 states “The product shall demonstrate at least 3 decimal log (lg) reduction” and will be amended to “The product shall demonstrate at least 3.00 decimal log (lg) reduction”. Then, a result of 2.87 is considered a fail to pass the standard.

All the efficacy EN standards indicate in Clause 4 the requirements to pass the norm (pass criteria). Currently, these requirements are expressed with 1 significant figure. The plan is to amend this way to express the requirements in Clause 4 to have 3 significant Figures (2 figures after the coma) in all European Standards.

4.2.11 N-numbers: round off the results calculated to two figures. For this, if the last figure is below 5, the preceding figure is not modified; if the last figure is 5 or more than 5, the preceding figure is increased by one unit. Proceed stepwise until two significant figures are obtained. As a result, the number of cfu/ml is expressed by a number between 1,0 and 9,9 multiplied by the appropriate power of 10.

4.2.12 Some efficacy European Standards indicate to perform sterile filtration using a filter of 0,45 µm pore size. However, sterile filtration is performed with pore sizes of 0,22 µm or 0,2 µm and this should be followed in all standards in this TC.

4.3 Chemical disinfectants and antiseptics for use in the medical area

4.3.1 General

In order to make a claim that a product including those considered as medical devices, has disinfectant properties, suitable for use in the medical area, the product shall be tested in accordance with and shall conform to the relevant European Standards as given in Table 1 and 2 as specified for the particular type of product and its spectrum of activity (e.g. bactericidal, fungicidal etc.). Table 1 and 2 include the information on standards in preparation or planned (see also Annex F).

Table 1 — Medical area – Standard test methods for substantiating product claims

Type of activity	Phase, step	Product Claim / Field of Application								
		Hygienic Handrub	Hygienic Handwash	Surgical Handrub or -wash	Surface Disinfection			Instrument Disinfection	Textile Disinfection	Aqueous systems
					mechanical action		Air-borne			
					without	With				
Bactericidal	2,1	EN 13727 (handrub products under clean, handwash products under dirty conditions)			EN 13727		***	EN 13727	**	***
	2,2	EN 1500	EN 1499	EN 12791	EN 17387	EN 16615	EN 17272	EN 14561	EN 16616	***
Yeasticidal	2,1	EN 13624 (handrub products under clean, handwash products under dirty conditions)			EN 13624		***	EN 13624	EN 13624	***
	2,2	***			EN 17387	EN 16615	EN 17272	EN 14562	EN 16616	***
Fungicidal	2,1	***			EN 13624		***	EN 13624	EN 13624	***
	2,2	***			EN 17387	*	EN 17272	EN 14562	EN 16616	***
Tuberculo-cidal	2,1	EN 14348	EN 14348	***	EN 14348		***	EN 14348	EN 14348 (dirty cond.)	***
	2,2	***			**		EN 17272	EN 14563	EN 16616	***
Mycobactericidal	2,1	EN 14348	EN 14348	***	EN 14348		***	EN 14348	EN 14348 (dirty cond.)	***
	2,2	***			**	*	EN 17272	EN 14563	EN 16616	***
Virus-cidal against enveloped viruses	2,1	EN 14476	EN 14476 (dirty cond.)	***	EN 14476		***	EN 14476	EN 14476	***
	2,2	**	**	***	EN 16777	*	***	EN 17111	EN 14476	***
Limited spectrum virus-cidal	2,1	EN 14476	**	***	EN 14476		***	***	**	***
	2,2	EN 17430	**	***	EN 16777	*	***	***	**	***
Virus-cidal	2,1	EN 14476	**	***	EN 14476		***	EN 14476	EN 14476	***
	2,2	EN 17430	***	***	EN 16777	*	EN 17272	EN 17111	**	***
Sporicidal against <i>C. diff.</i>	2,1	***			EN 17126		***	EN 17126	EN 17126	***
	2,2	***			**	EN 17846	***	**	***	***
Sporicidal	2,1	***			EN 17126		***	EN 17126	EN 17126	***
	2,2	***			**	**	EN 17272	**	***	***
<i>Legionella</i>	2,1	***			***		***	***	***	EN 13623
	2,2	***			***		***	***	***	***
* Work item approved (see Annex F).										
** No work item yet approved but relevant standards could become available in the future										
*** No intention to develop a test										

Table 2 — Medical area – Medical devices – Standard test methods for substantiating product claims

Type of activity	Phase, step	Product Claim / Field of Application			
		Surface Disinfection		Instrument Disinfection	Textile Disinfection
		mechanical action			
		without	with		
Bactericidal	2,1	EN 13727		EN 13727	**
	2,2	EN 17387	EN 16615	EN 14561	EN 16616
Yeasticidal	2,1	EN 13624		EN 13624	EN 13624
	2,2	EN 17387	EN 16615	EN 14562	EN 16616
Fungicidal	2,1	EN 13624		EN 13624	EN 13624
	2,2	EN 17387	*	EN 14562	EN 16616
Tuberculocidal	2,1	EN 14348		EN 14348	EN 14348 (dirty cond.)
	2,2	**	*	EN 14563	EN 16616
Mycobactericidal	2,1	EN 14348		EN 14348	EN 14348 (dirty cond.)
	2,2	**	*	EN 14563	EN 16616
Virucidal against enveloped viruses	2,1	EN 14476		EN 14476	EN 14476
	2,2	EN 16777	*	EN 17111	**
Limited spectrum virucidal	2,1	EN 14476		***	**
	2,2	EN 16777	*	***	**
Virucidal	2,1	EN 14476		EN 14476	EN 14476
	2,2	EN 16777	*	EN 17111	**
Sporicidal against <i>C. diff.</i>	2,1	EN 17126		EN 17126	EN 17126
	2,2	**	EN 17846	**	***
Sporicidal	2,1	EN 17126		EN 17126	EN 17126
	2,2	**	**	**	***
* Work item approved (see Annex F).					
** No work item yet approved but relevant standards could become available in the future					
*** No intention to develop a test					

As stated under 4.1, phase 2, step 1 and phase 2, step 2 tests shall be passed for any claim if standards are available. All products in the medical area shall pass the standards for bactericidal and yeasticidal activity as a minimum requirement except those products exclusively claiming activity against *Legionella* or fungicidal or sporicidal activity. A summary of the test conditions and requirements for the relevant phase 2, step 1 and phase 2, step 2 tests is given in 4.3.2 and in Tables 3, 4, 5 and 6. It is also stated, if for a certain field of application more than one standard shall be passed (see also Annex C).

4.3.2 Fields of application / Standards necessary to be passed for basic and additional label claims

4.3.2.1 General

In 4.3.2.2 to 4.3.2.9 the obligatory and additional standards for a defined claim are described. The Tables 3, 4, 5, 6 and 7 (4.3.4) give an overview of the standards relevant for the medical area and their main features, such as test organisms, temperature, soiling, contact time and reduction. The Clauses 4.3.2.5, 4.3.2.6, 4.3.2.7 and 4.3.2.8 shall be used for medical devices. The term “soiling” means always the soiling used within the medical area (e.g. 5.2.2.8 in EN 13727) even if a standard from another area (e.g. food) is used according to 4.2.5.1. In Table 6 specific aspects how to use EN 14348 for the different fields of application are laid down.

Laboratories and veterinary care facilities are covered by the standards for the medical area in case of hygienic handrub and handwash, surgical handrub and handwash.

NOTE The additional standard needed will depend on the intended use of the product. Please refer to national or European guidelines where they exist.

4.3.2.2 Hygienic handrub

European Standards to be passed	
Bactericidal activity	EN 13727 (2/1), EN 1500 (2/2)
Yeasticidal activity	EN 13624 (2/1)
Additional European Standards	
Tuberculocidal / Mycobactericidal activity	EN 14348 (2/1)
Virucidal activity against enveloped viruses /	EN 14476 (2/1)
Limited spectrum virucidal activity / Virucidal activity	EN 14476 (2/1), EN 17430 (2/2)

NOTE Activity on mould spores is not regarded relevant for hygienic handrub products.

4.3.2.3 Hygienic handwash

European Standards to be passed	
Bactericidal activity	EN 13727 (2/1), EN 1499 (2/2)
Yeasticidal activity	EN 13624 (2/1)
Additional European Standards	
Tuberculocidal/Mycobactericidal activity	EN 14348 (2/1)
Virucidal activity against enveloped viruses	EN 14476 (2/1) ^a
^a efficacy testing of 50 % product dilution in analogy to EN 13727 and EN 13624 (with a 2 lg reduction)	

NOTE Activity on mould spores is not regarded relevant for hygienic handwash products.

4.3.2.4 Surgical handrub and handwash

European Standards to be passed	
Bactericidal activity	EN 13727 (2/1), EN 12791 (2/2)
Yeasticidal activity	EN 13624 (2/1)

NOTE Activity on mould spores, mycobacteria and viruses, is not regarded relevant for surgical handrub and surgical handwash according to the state of the art.

4.3.2.5 Instrument disinfection

European Standards to be passed	
Bactericidal activity	EN 13727 (2/1), EN 14561 (2/2)
Yeasticidal activity	EN 13624 (2/1), EN 14562 (2/2)
Additional European Standards	
Fungicidal activity	EN 13624 (2/1), EN 14562 (2/2)
Tuberculocidal / Mycobactericidal activity	EN 14348 (2/1), EN 14563 (2/2)
Virucidal activity against enveloped viruses / Virucidal activity	EN 14476 (2/1), EN 17111 (2/2)
Sporicidal activity against <i>C. diff.</i> / Sporicidal activity	EN 17126 (2/1)

4.3.2.6 Surface disinfection without mechanical action

European Standards to be passed	
Bactericidal activity	EN 13727 (2/1), EN 17387 (2/2)
Yeasticidal activity	EN 13624 (2/1), EN 17387 (2/2)
Additional European Standards	
Fungicidal activity	EN 13624 (2/1), EN 17387 (2/2)
Tuberculocidal/Mycobactericidal activity	EN 14348 (2/1)
Virucidal activity against enveloped viruses / Limited spectrum virucidal activity / Virucidal activity	EN 14476 (2/1), EN 16777 (2/2)
Sporicidal activity against <i>C. diff.</i> / Sporicidal activity	EN 17126 (2/1)

4.3.2.7 Surface disinfection with mechanical action

European Standards to be passed	
Bactericidal activity	EN 13727 (2/1), EN 16615 (2/2)
Yeasticidal activity	EN 13624 (2/1), EN 16615 (2/2)
Additional European Standards	
Fungicidal activity	EN 13624 (2/1)
Tuberculocidal/Mycobactericidal activity	EN 14348 (2/1)
Virucidal activity against enveloped viruses / Limited spectrum virucidal activity /Virucidal activity	EN 14476 (2/1)
Sporicidal activity against <i>C. diff.</i> / Sporicidal activity	EN 17126 (2/1), EN 17846 (2/2)

4.3.2.8 Textile disinfection

European Standards to be passed	
Bactericidal activity	EN 13727 (2/1, dirty conditions), EN 16616 (2/2)
Yeasticidal activity	EN 13624 (2/1, dirty conditions), EN 16616 (2/2)
Additional European Standards	
Fungicidal activity	EN 13624 (2/1, dirty conditions), EN 16616 (2/2)
Tuberculocidal / Mycobactericidal activity	EN 14348 (2/1, dirty conditions), EN 16616 (2/2)
Virucidal activity	EN 14476 (2/1, dirty conditions)
Sporicidal activity against <i>C. diff.</i> / Sporicidal activity	EN 17126 (2/1, dirty conditions)

4.3.2.9 Water treatment for control of Legionella

See EN 13623 in Table 3 below.

4.3.3 Medical Devices – standards applicable for basic and additional label claims

A product manufacturer's claims determine which clauses of the standard are to be used in case of medical devices:

- If the product claims instrument disinfection through submersion, 5.3.2.5 and the corresponding column in Table 2 are to be followed.
- If the product claims medical device surface disinfection without the use of mechanical action, 5.3.2.6 and the corresponding column in Table 2 are to be followed.
- If the product claims medical device surface disinfection with the use of mechanical action, 5.3.2.7 and the corresponding column in Table 2 are to be followed.
- If the product claims medical device textile disinfection, 5.3.2.8 and the corresponding column in Table 2 are to be followed.

Tables 3, 4, 5, 6 and 7 (4.3.4) give an overview of the standards relevant for the medical area and their main features, such as test organisms, temperature, soiling, contact time and reduction.

4.3.4 Overview of the standards relevant for the medical area and their main features

Table 3 — Medical area – Test conditions and requirements of standard test methods for bactericidal activity of products

EN reference Phase, step	Test organisms	Temperature °C	Contact time	Interfering substances	Logarithmic reduction expressed in lg
EN 1499 2,2	Minimum test conditions				
	<i>Escherichia coli</i> K12, NCTC 10538 (=NCIMB 10083)	tested on the skin	between 30 s and 1 min	none	product > reference soap with 1 min wash (<i>p</i> = 0,01)
EN 1500 2,2	Minimum test conditions				
	<i>Escherichia coli</i> K12, NCTC 10538	tested on the skin	between 30 s and 1 min	none	product not < Propan-2-ol 60 % vol with 2 × 3 ml/30 s each (<i>p</i> = 0,025)
EN 12791 2,2	Minimum test conditions				
	normal skin flora	tested on the skin	between 1 min and 5 min	none	<u>Immediate effect:</u> product not < Propan-1-ol 60 % vol with n × 3 ml/3 min (<i>p</i> = 0,025)
					<u>3-h-effect:</u> product not < Propan-1-ol 60 % vol (<i>p</i> = 0,025)
	Additional test conditions				
	none	none	none	none	<u>Sustained effect:</u> product > Propan-1-ol 60 % vol with n × 3 ml/3 min after 3 h (<i>p</i> = 0,01)
EN 13727 2,1	Hygienic handwash and handrub minimum test conditions				
	<i>Staphylococcus aureus</i> ATCC 6538 <i>Pseudomonas aeruginosa</i> ATCC 15442	20	between 30 s and 1 min	<u>Clean conditions (handrub):</u> bovine albumin: 0,3 g/l	≥ 5 for handrub products