STN	**Chemické dezinfekčné a antiseptické prípravky Kvantitatívna suspenzná skúška na vyhodnotenie virulocídnej aktivity pre chemické dezinfekčné a antiseptické prípravky používané v oblasti medicíny Skúšobná metóda a požiadavky (fáza 2, krok 1)**	**STN EN 14476** 85 7029

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)

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

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 01/26

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English Version

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)

Antiseptiques et désinfectants chimiques - Essai quantitatif de suspension pour l'évaluation de l'activité virucide dans le domaine médical - Méthode d'essai et exigences (Phase 2/Étape 1)

Chemische Desinfektionsmittel und Antiseptika - Quantitativer Suspensionsversuch zur Bestimmung der viruziden Wirkung im humanmedizinischen Bereich - Prüfverfahren und Anforderungen (Phase 2, Stufe 1)

This European Standard was approved by CEN on 20 July 2025.

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

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European foreword

This document (EN 14476:2025) has been prepared by Technical Committee CEN/TC 216 “Chemical disinfectants and antiseptics”, the secretariat of which is held by AFNOR.

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of an identical text or by endorsement, at the latest by April 2026, and conflicting national standards shall be withdrawn at the latest by April 2026.

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.

This document supersedes EN 14476:2013+A2:2019.

This document was revised to adapt it to the latest state of science, to correct errors and ambiguities, to harmonize the structure and wording with other existing tests of CEN/TC 216 or in preparation and to improve its readability and thereby make it more understandable.

EN 14476:2025 includes the following significant technical changes with respect to EN 14476:2013+A2:2019:

— de-harmonization of the standard (Annex ZA and references to MDR/MDD deleted);

— for textile disinfection and instrument disinfection a test for virucidal activity against enveloped viruses with vaccinia virus has been added;

— Glutaraldehyde has been added as an alternative reference substance to formaldehyde;

— for chemothermal disinfection e.g. textile disinfection peracetic acid has been added as reference substance;

— for the hygienic handrub and handwash claims, a test for virucidal activity against enveloped viruses with vaccinia virus was added with specific lg reduction requirement for handwash products;

— the calculation was shifted to the main text (harmonized with EN 13727);

— the LVP method was shifted to the main text;

— it was clarified that given cell line numbers are only examples;

— for hygienic handrubs, adenovirus shall be tested at (25 ± 1) °C;

— spelling errors and incorrect references were corrected.

The changes of this revision have no impact on the test results obtained with reference to the version EN 14476:2013+A2:2019. Those results are still valid with the exception of test reports using gel filtration detoxification, which do not provide a parallel titration of the non-filtrated test mixture. Additional comparison between unfiltered and filtrated test mixture shall be added in the test report using gel filtration detoxification.

Test results for hygienic handrub products tested at 20 °C with adenovirus in accordance with the previous version are still valid.

Other methods to evaluate the efficacy of chemical disinfectants and antiseptics for different applications in the medical area are in preparation.

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 organisations 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 suspension test for establishing whether a chemical disinfectant or an antiseptic has a virucidal activity in the area and fields described in the scope.

This laboratory test takes into account practical conditions of application of the product including contact time, temperature, test organisms and interfering substances, i.e. conditions which can influence its action in practical situations. Each utilization concentration of the chemical disinfectant or antiseptic found by this test corresponds to the chosen experimental conditions.

1 Scope

This document specifies a test method and the minimum requirements for virucidal activity of chemical disinfectant and antiseptic products that form a homogeneous physically stable preparation when diluted with hard water – or in the case of ready-to-use products, i.e. products that are not diluted when applied, – with water. Ready-to-use-products can only be tested at a concentration up to 80 % (97 %, with a modified method for special cases) as some dilution is always produced by adding the test organisms and interfering substance.

This document is applicable to products that are used in the medical area in the fields of hygienic handrub, hygienic handwash, instrument disinfection by immersion, surface disinfection by wiping, spraying, flooding or other means and textile disinfection.

This document is applicable to areas and situations where disinfection is medically indicated. Such indications occur in patient care, for example:

— in hospitals, in community medical facilities, and in dental institutions;

— in clinics of schools, of kindergartens, and of nursing homes;

and can occur in the workplace and in the home. It can also include services such as laundries and kitchens supplying products directly for the patient.

NOTE 1 The method described is intended to determine the activity of commercial formulations or active substances under the conditions in which they are used.

NOTE 2 This method corresponds to a phase 2, step 1 test.

NOTE 3 EN 14885 specifies in detail the relationship of the various tests to one another and to “use recommendations”.

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,[1] *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 14885,[1] *Chemical disinfectants and antiseptics — Application of European Standards for chemical disinfectants and antiseptics*

[1] EN 12353, and EN 14885 are updated on an ongoing basis as the standards to which they refer are developed and evolve. As the revision of both standards is much more frequent than the updating of this standard, the standards are not dated. Users should refer to the latest version of the referenced standards.