

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. 04/18

Obsahuje: EN 12791:2016+A1:2017

Oznámením tejto normy sa ruší STN EN 12791 (85 7030) z júla 2016 STN EN 12791+A1: 2018

EUROPEAN STANDARD NORME EUROPÉENNE EUROPÄISCHE NORM

EN 12791:2016+A1

November 2017

ICS 11.080.20

Supersedes EN 12791:2016

English Version

Chemical disinfectants and antiseptics - Surgical hand disinfection - Test method and requirements (phase 2, step 2)

Antiseptiques et désinfectants chimiques - Désinfection chirurgicale des mains - Méthodes d'essai et prescriptions (phase 2/étape 2)

Chemische Desinfektionsmittel und Antiseptika -Chirurgische Händedesinfektionsmittel - Prüfverfahren und Anforderungen (Phase 2, Stufe 2)

This European Standard was approved by CEN on 13 December 2015 and includes Amendment 1 approved by CEN on 20 July 2017.

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, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.



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

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

EN 12791:2016+A1:2017 (E)

Contents		Page
European foreword3		
1	Scope	4
2	Normative references	4
3	Terms and definitions	4
4	Requirements	
5	Test methods	
5.1	Principle	
5.2	Materials and reagents	
5.2.1	Test organism	
5.2.2	Culture media and reagents	
5.3	Apparatus and glassware	
5.3.1	General	
5.3.2	Usual microbiological laboratory equipment	
5.4 5.5	Product test solutions Procedure for assessing the microbicidal activity of the product on volunteers'	8
5.5	hands	0
5.5.1	General	
5.5.1 5.5.2	Preparatory handwash	
5.5.2 5.5.3	1 V	
5.5.4	Test procedure with volunteers Incubation and counting of the test mixture	
	Experimental data and calculation	
5.6 5.6.1	Determination of V_c -values	
5.6.1	· · · · · · · · · · · · · · · · · · ·	
5.6.4 5.7	Calculation of the individual lg reduction (lg R; lg prevalue minus lg postvalue)	
5.7. 1	Verification of the methodology	
_	Acceptance criteria for test results	
5.7.2	Control of weighted mean counts	
5.8	Statistical evaluation (significance testing), expression of results and precision	
5.9	Conclusion	
5.10	Test report	
Annex A (informative) Standard surgical handrub/-wash procedure		17
Annex	B (informative) Quality control of soft soap	18
Annex	C (informative) Examples of reporting of results and significance testing	19
Annex	D (informative) WILCOXON'S matched-pairs signed-ranks test	30
Bibliography		31

EN 12791:2016+A1:2017 (E)

European foreword

This document (EN 12791:2016+A1:2017) 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 May 2018, and conflicting national standards shall be withdrawn at the latest by May 2018.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document includes Amendment 1 approved by CEN on 2017-07-20.

This document supersedes A EN 12791:2016 A.

The start and finish of text introduced or altered by amendment is indicated in the text by tags [A].

A_1 deleted text A_1

Data obtained using the former version of EN 12791 may still be used, if it is supplemented by data on neutralization, additional results from more volunteers and the new statistical evaluation of the "mixed" (old and new) set of data. The additional results should be obtained preferably in the same laboratory and with volunteers not having participated in the previous ("old") study. If the neutralizer used in the test using the former version is not sufficiently neutralizing a complete new test should be run.

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, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

1 Scope

This European Standard specifies a test method simulating practical conditions for establishing whether a product for surgical handrub and handwash reduces the release of resident and eventually present transient microbial flora on hands when used for the treatment of clean hands of volunteers.

This European Standard applies to products for surgical handrub or handwash for use in 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 may occur in the workplace and in the home. It may also include services such as laundries and kitchens supplying products directly for the patient.

EN 14885 specifies in detail the relationship of the various tests to one another and to "use recommendations".

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

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN 13624, 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 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 14885, Chemical disinfectants and antiseptics — Application of European Standards for chemical disinfectants and antiseptics

koniec náhľadu – text ďalej pokračuje v platenej verzii STN