

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

## EESTI STANDARDI EESSÕNA

## NATIONAL FOREWORD

See Eesti standard EVS-EN 12791:2016 sisaldab Euroopa standardi EN 12791:2016 ingliskeelset teksti.	This Estonian standard EVS-EN 12791:2016 consists of the English text of the European standard EN 12791:2016.
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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.

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COMITÉ EUROPÉEN DE NORMALISATION  
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## European foreword

This document (EN 12791:2016) 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of an identical text or by endorsement, at the latest by August 2016, and conflicting national standards shall be withdrawn at the latest by August 2016.

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 supersedes EN 12791:2005.

It was revised to adapt it to the latest state of science, to correct errors and ambiguities, to harmonize the structure and wording with other tests of CEN TC 216 existing or in preparation and to improve the readability of the standard and thereby make it more understandable. The following technical changes have been made:

- neutralization (5.5.1.2);
- the number of volunteers (5.5.1.4);
- no rinse after the disinfection (5.5.3.2.2);
- the statistical evaluation (5.8);
- the annexes have been completely revised.

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, 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*

## 3 Terms and definitions

For the purposes of this document, the terms and definitions given in EN 14885 apply.

## 4 Requirements

The mean reduction for immediate effect and 3 h effect of a product shall - when tested in accordance with Clause 5 - at least be not inferior to that achieved by a specified reference product (60 % volume concentration of propan-1-ol).

To demonstrate additionally a “sustained effect”, the mean reduction for the 3 h effect of a product shall be superior to that achieved by the reference product.

## 5 Test methods

### 5.1 Principle

A specified preparatory handwash (pre-wash) is carried-out on volunteers in order to remove most of the transient flora and foreign material, which could otherwise influence the “prevalues”, i.e. the