

**NAMS 14563:2024**

First Edition

**EN 14563:2008**

## **NAMIBIAN STANDARD**

# **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)**

This Namibian standard is the identical adoption of EN 14563:2008 and is adopted with the permission of the European Committee for Standardization

---

Published by the Namibian Standards Institution (NSI)  
**Established by section 2 of the Standards Act, 2005 (Act No 18 of 2005)**  
37 Feld Street  
P.O. Box 26364 Windhoek, Namibia  
Tel +264-61386400, Fax +264-61-386454  
Website: [www.nsi.com.na](http://www.nsi.com.na)  
© NSI



Licensed by NSI to NSI for internal use only  
DOWNLOADED:24/06/2026  
Single-user licence only, copying and networking prohibited.

# **NAMS 14563:2024**

First Edition

## **EN 14563:2008**

### **National foreword**

This Namibian Standard (NAMS) is identical to EN 14563:2008, and was approved for adoptions by the Namibian Standards Institution CEO.

Namibian standards are developed based on NSI Standards development procedures in accordance with the rules given in the International Organisation for Standardisation/ International Electrotechnical Commission (ISO/IEC) Directives 1, ISO/IEC Guide 21-1 Adoption of international standards as regional or national standards and WTO – TBT World Trade Organisation code of Good Practice (which is published as Annex 3 in the TBT Agreement)

The NSI Technical Committee responsible for this standard is NSI TC 14, Chemicals.

This NAMS 14563:2024 EN 14563:2008 was published in May 2024.

English Version

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)

Désinfectants et antiseptiques chimiques - Essai quantitatif  
de porte-germe pour l'évaluation de l'activité  
mycobactéricide ou tuberculocide des désinfectants  
chimiques utilisés pour instruments en médecine humaine -  
Méthode d'essai et prescriptions (phase 2, étape 2)

Chemische Desinfektionsmittel und Antiseptika -  
Quantitativer Keimträgerversuch zur Prüfung der  
mykobakteriziden oder tuberkuloziden Wirkung chemischer  
Desinfektionsmittel für Instrumente im  
humanmedizinischen Bereich - Prüfverfahren und  
Anforderungen (Phase 2, Stufe 2)

This European Standard was approved by CEN on 18 October 2008.

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 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 Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.



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

Management Centre: rue de Stassart, 36 B-1050 Brussels

## Contents

Page

Foreword.....	3
Introduction .....	4
1 <b>Scope</b> .....	5
2 <b>Normative references</b> .....	5
3 <b>Terms and definitions</b> .....	5
4 <b>Requirements</b> .....	5
5 <b>Test method</b> .....	6
5.1 <b>Principle</b> .....	6
5.2 <b>Materials and reagents</b> .....	6
5.3 <b>Apparatus and glassware</b> .....	9
5.4 <b>Preparation of test organism suspensions and product test solutions</b> .....	11
5.5 <b>Procedure for assessing the mycobactericidal / tuberculocidal activity of the product</b> .....	13
5.6 <b>Experimental data and calculation</b> .....	16
5.7 <b>Verification of methodology</b> .....	22
5.8 <b>Expression of results and precision</b> .....	22
5.9 <b>Interpretation of results – conclusion</b> .....	23
5.10 <b>Test report</b> .....	24
<b>Annex A (informative) Referenced strains in national collections</b> .....	26
<b>Annex B (informative) Examples of neutralizers of the residual antimicrobial activity of chemical disinfectants and antiseptics and rinsing liquids</b> .....	27
<b>Annex C (informative) Graphical representations of the test method</b> .....	29
<b>Annex D (informative) Example of a typical test report</b> .....	32
<b>Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC</b> .....	35
<b>Bibliography</b> .....	36

## Foreword

This document (EN 14563:2008) 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 2009, and conflicting national standards shall be withdrawn at the latest by May 2009.

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 has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EC Directive(s).

For relationship with EU Directive 93/42/EEC, see informative annex ZA, which is an integral part of this document.

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

A collaborative trial will be undertaken to provide a precision annex to this standard.

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, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

## Introduction

This European Standard specifies a carrier test for establishing whether a chemical disinfectant for use on instruments (surgical instruments, anaesthesia material, endoscopes etc.) has a mycobactericidal or tuberculocidal activity in the area described in the scope.

The laboratory test closely simulates practical conditions of application including pre-drying mycobacteria on a carrier, contact time, temperature, test organisms and interfering substances, i.e. conditions which may influence the action of chemical disinfectants in practical situations.

The obligatory conditions are intended to cover general purposes and to allow reference between laboratories and product types. Each utilization concentration of the chemical disinfectant found by this test corresponds to defined experimental conditions. However, for some applications the recommendations of use of a product may differ and therefore additional test conditions need to be used.