

Surgical and dental hand instruments - Determination of resistance against autoclaving, corrosion and thermal exposure (ISO 13402:2025)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

<p>See Eesti standard EVS-EN ISO 13402:2025 sisaldab Euroopa standardi EN ISO 13402:2025 ingliskeelset teksti.</p> <p>Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.</p> <p>Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 19.03.2025.</p> <p>Standard on kättesaadav Eesti Standardimis- ja Akrediteerimiskeskusest.</p>	<p>This Estonian standard EVS-EN ISO 13402:2025 consists of the English text of the European standard EN ISO 13402:2025.</p> <p>This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation.</p> <p>Date of Availability of the European standard is 19.03.2025.</p> <p>The standard is available from the Estonian Centre for Standardisation and Accreditation.</p>
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ICS 11.040.30, 11.060.25

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EUROPEAN STANDARD

EN ISO 13402

NORME EUROPÉENNE

EUROPÄISCHE NORM

March 2025

ICS 11.040.30; 11.060.25

Supersedes EN ISO 13402:2000

English Version

Surgical and dental hand instruments - Determination of resistance against autoclaving, corrosion and thermal exposure (ISO 13402:2025)

Instruments chirurgicaux et dentaires à main -
Détermination de la résistance au passage à
l'autoclave, à la corrosion et à l'exposition à la chaleur
(ISO 13402:2025)

Chirurgische und zahnärztliche Handinstrumente -
Bestimmung der Beständigkeit gegenüber Sterilisation,
Korrosion und Wärmebehandlung (ISO 13402:2025)

This European Standard was approved by CEN on 2 March 2025.

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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

European foreword

This document (EN ISO 13402:2025) has been prepared by Technical Committee ISO/TC 170 "Surgical instruments" in collaboration with Technical Committee CEN/TC 55 "Dentistry" the secretariat of which is held by DIN.

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of an identical text or by endorsement, at the latest by September 2025, and conflicting national standards shall be withdrawn at the latest by September 2025.

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 ISO 13402:2000.

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Endorsement notice

The text of ISO 13402:2025 has been approved by CEN as EN ISO 13402:2025 without any modification.

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 170, *Surgical instruments*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 55, *Dentistry*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 13402:1995), which has been technically revised.

The main changes are as follows:

- restructuring of the document;
- update of [Clause 2](#);
- addition of [Clause 3](#);
- addition of [Clause 4](#) including a table with an overview of test methods;
- addition of [Clause 5](#);
- addition of [Annexes A](#) to [H](#) including test methods.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

The procedures described in this document form a harmonized series of tests that can be referred to, individually or in combination, in other separate product standards. The requirements for such tests are defined and stated within the body of the product standard along with the number of cycles for each test procedure. The tests apply to dental and surgical instruments and are already standardized in relevant product standards (e.g. ISO 7151, ISO 9173-1). However, the test procedures as stated in the product standards differ in minor details. An alignment and a compilation were established.

The most important test methods for dental and surgical instruments have been compiled in this document.

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Surgical and dental hand instruments — Determination of resistance against autoclaving, corrosion and thermal exposure

1 Scope

This document describes test methods to determine the resistance of stainless steel surgical and dental hand instruments against autoclaving, corrosion and thermal exposure.

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.

ISO 3696, *Water for analytical laboratory use — Specification and test methods*

ISO 7554-3, *Surgical instruments — Terms, measuring methods and tests — Part 3: Test methods*¹⁾

EN 13018, *Non-destructive testing — Visual testing — General principles*

3 Terms and definitions

No terms and definitions are listed in this document.

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

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

4 Test methods

4.1 General

All tests are type tests.

4.2 Sampling plan

- a) Each instrument manufacturer shall define an appropriate sampling plan for ensuring instrument safety and quality. The sampling shall be done according to ISO 7554-3.
- b) Rejected lots are often re-passivated and re-tested, typically using an increased sample size of instruments. If the lot is rejected a second time, the cause of the repeat failure should be evaluated before proceeding.

1) Under preparation. Stage at the time of publication: ISO/DIS 7664-3.