

Chirurgické a stomatologické nástroje Stanovenie odolnosti proti pôsobeniu v autokláve, korózii a pôsobeniu tepla (ISO 13402: 2025)

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

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

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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)

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

EN ISO 13402:2025 (E)

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of an identical text or by endorsement, at the latest by September 2025, and conflicting national standards shall be withdrawn at the latest by September 2025.

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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.



International Standard

ISO 13402

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

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

Second edition 2025-03



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Foreword

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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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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 <u>Clause 2</u>;
- addition of Clause 3:
- addition of <u>Clause 4</u> including a table with an overview of test methods;
- addition of Clause 5;
- addition of Annexes A to $\underline{\mathbf{H}}$ 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.

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 methods¹⁾

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

koniec náhľadu – text ďalej pokračuje v platenej verzii STN

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