SLOVENSKI STANDARD
SIST EN ISO 13402:2025

01-maj-2025

Nadomešča:
SIST EN ISO 13402:2001

Kirurški in zobozdravstveni ročni instrumenti - Določanje odpornosti proti avtoklaviranju, koroziji in toplotni izpostavljenosti (ISO 13402:2025)

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

Chirurgische und zahnärztliche Handinstrumente - Bestimmung der Beständigkeit gegenüber Sterilisation, Korrosion und Wärmebehandlung (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)

Ta slovenski standard je istoveten z: **EN ISO 13402:2025**

ICS:

11.040.30	Operacijski instrumenti in materiali	Surgical instruments and materials
11.060.25	Zobotehnični instrumenti	Dental instruments

SIST EN ISO 13402:2025 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 13402

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

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of an identical text or by endorsement, at the latest by September 2025, and conflicting national standards shall be withdrawn at the latest by September 2025.

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.

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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

Second edition
2025-03

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

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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.