

SLOVENSKI STANDARD
SIST EN ISO 13402:2001**01-november-2001**

Surgical and dental hand instruments - Determination of resistance against autoclaving, corrosion and thermal exposure (ISO 13402:1995)

Surgical and dental hand instruments - Determination of resistance against autoclaving, corrosion and thermal exposure (ISO 13402:1995)

Chirurgische und zahnärztliche Handinstrumente - Bestimmung der Beständigkeit gegenüber Sterilisation, Korrosion und Wärmebehandlung (ISO 13402:1995)

Instruments chirurgicaux et dentaires a main - Détermination de la résistance au passage a l'autoclave, a la corrosion et a l'exposition a la chaleur (ISO 13402:1995)

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Ta slovenski standard je istoveten z: EN ISO 13402:2000

ICS:

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

SIST EN ISO 13402:2001**en**

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 13402

October 2000

ICS 11.040.30; 11.060.20

English version

Surgical and dental hand instruments - Determination of
resistance against autoclaving, corrosion and thermal exposure
(ISO 13402:1995)

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 13402:1995)

Chirurgische und zahnärztliche Handinstrumente -
Bestimmung der Beständigkeit gegenüber Sterilisation,
Korrosion und Wärmebehandlung (ISO 13402:1995)

This European Standard was approved by CEN on 9 September 2000.

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 Central Secretariat 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 Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

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

Central Secretariat: rue de Stassart, 36 B-1050 Brussels

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EN ISO 13402:2000

Foreword

The text of the International Standard from Technical Committee ISO/TC 170 "Surgical instruments" of the International Organization for Standardization (ISO) has been taken over as an European Standard by 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 April 2001, and conflicting national standards shall be withdrawn at the latest by April 2001.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of the International Standard ISO 13402:1995 has been approved by CEN as a European Standard without any modification.

NOTE: Normative references to International Standards are listed in annex ZA (normative).

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Annex ZA (normative)
Normative references to international publications
with their relevant European publications

This European Standard incorporates, by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text, and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN</u>	<u>Year</u>
ISO 3696	1987	Water for analytical laboratory use - Specification and test methods	EN ISO 3696	1995

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INTERNATIONAL
STANDARD

ISO
13402

First edition
1995-08-01

**Surgical and dental hand instruments —
Determination of resistance against
autoclaving, corrosion and thermal
exposure**
iTeh STANDARD PREVIEW
(standards.iteh.ai)

*Instruments chirurgicaux et dentaires à main — Détermination de la
résistance au passage à l'autoclave, à la corrosion et à l'explosion à la
chaleur*
<https://standards.iteh.ai/catalog/standards/sist/7c517ad0-7def-407d-8b46-28e1b922bc09/sist-en-iso-13402-2001>



Reference number
ISO 13402:1995(E)

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.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

International Standard ISO 13402 was prepared by Technical Committee ISO/TC 170, *Surgical instruments*.

Annex A of this International Standard is for information only.

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Introduction

The procedures described in this International Standard are intended to form a harmonized series of tests that may be referred to, individually or in combination, in other separate product standards. The requirements for such tests shall be 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, *Surgical instruments — Non-cutting, articulated instruments — General requirements and test methods*; ISO 9173-1 *Dental extraction forceps — Part 1: Screw and pin joint types*). However, the test procedures as stated in the product standards differ in minor details. An alignment and a compilation was established. The most important test methods for dental and surgical instruments have been brought together in one general International Standard.

Other, additional, tests may also be required in individual product standards; those procedures and requirements will be determined by the members of the working groups concerned. When established, it is intended that these additional test procedures are incorporated in this International Standard as an addendum or at the next revision.

This International Standard does not specify any test sequence nor any requirements related to specific instruments. The requirements, the test sequence and the number of test cycles have to be defined in the relevant product standards or, if no standard is available, it has to be left to the decision of the purchaser and/or the manufacturer.

Apart from the boiling water test, the autoclave test applies for determining corrosion resistance. In this sense, this International Standard specifies two test methods for determining corrosion resistance. When placing an order, it is intended that the purchaser state whether both tests are to be carried out or which of the two tests. If the purchaser does not so indicate, the choice is left to the discretion of the manufacturer.