SLOVENSKI STANDARD
oSIST prEN ISO 13402:2024

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Nadomešča:
SIST EN ISO 13402:2001

Kirurški in zobozdravstveni ročni instrumenti - Določanje odpornosti proti avtoklaviranju, koroziji in toplotni izpostavljenosti (ISO/DIS 13402:2023)

Surgical and dental hand instruments - Determination of resistance against autoclaving, corrosion and thermal exposure (ISO/DIS 13402:2023)

Chirurgische und zahnärztliche Handinstrumente - Bestimmung der Beständigkeit gegenüber Sterilisation, Korrosion und Wärmebehandlung (ISO/DIS 13402:2023)

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/DIS 13402:2023)

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Ta slovenski standard je istoveten z: **prEN ISO 13402**

ICS:

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

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DRAFT INTERNATIONAL STANDARD

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ISO/TC **170**

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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

ICS: 11.040.30; 11.060.20

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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 documents 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*.

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

The main changes are as follows:

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— restructuring of the document;
— Update of Clause 2 “Normative references”;
— addition of Clause 3 “Terms and definitions”;
— Addition of clause 4 “General considerations” and addition of table Sampling plan and table 2 with an overview on test methods”;
— Addition of Clause 5 “Test report”.
— Addition of test methods in Annex A to Annex H.

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.

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Introduction

The procedures described in this document 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 7: 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 document.

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 document as an addendum or at the next revision. This document 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.

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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.

The requirements for such tests are defined and stated in the product Standard along with the number of cycles for each test procedure. Other, additional, tests may also be required (see the Introduction).

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.

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

EN 13060, *Small steam sterilizers*

ISO 3696:1987, *Water for analytical laboratory use — Specification and test methods*

ISO 15883, *— Washer-disinfectors — Part 1: General requirements, terms and definitions and tests*

ISO 17664, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices*

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3 Terms and definitions

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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 General considerations / principle

4.1 General

All test are type tests.

The test shall be performed using the procedure described table 1.

4.2 Sampling plan

1. Each instrument manufacturer shall define an appropriate sampling plan for ensuring instrument safety and quality.

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2. Rejected lots are often re-passivated and retested, typically using an increased sample size of instruments. If the lot is rejected a second time, it is recommended that the cause of the repeat failure be evaluated before proceeding.

Table 1 — Overview test principle, procedure and materials

Test method	Applicable for	Information received	Annex
Boiling test in deionized water	The boiling test is applicable to martensitic, austenitic, ferritic material with less than 16 % chromium, and precipitation hardening materials to detect surface imperfections, free iron, or other anodic surface contaminations on stainless steel. Instruments containing stainless steel materials that are exclusively to the following shall use the boil test **and** copper sulfate test: austenitic materials, precipitation hardening materials, and ferritic materials containing equal or greater than 16 % chromium.		Annex A (normative)
Boiling test in 0,9 % NaCl solution	only stainless steel materials: austenitic materials, precipitation hardening materials and ferritic materials with a chromium content of 16 % or more.		Annex B (normative)
Copper sulfate test	The copper sulfate test is applicable to martensitic, austenitic, ferritic material with less than 16 % chromium, and precipitation hardening materials to improper heat treatment. Instruments containing stainless steel materials that are exclusively to the following shall use the copper sulfate test and boil test: austenitic materials, precipitation hardening materials, and ferritic materials containing equal or greater than 16 % chromium.		Annex C (normative)
Test in 0,3 % NaCl solution	austenitic steel	Corrosion test exclusively for austenitic steels *e*	Annex D *(informative)*
Test with Citric acid solution	austenitic steel	Corrosion test exclusively for austenitic steels	Annex E *(informative)*
Test with KOR-ROPAD	martensitic steel austenitic steel	Testing the passive layer	Annex F *(informative)*
Thermal test	martensitic steel austenitic steel	Determination of resistance to thermal stress	Annex G *(informative)*
Autoclav test	martensitic steel austenitic steel	The sterilization test should simulate normal operating conditions.	Annex H *(normative)*

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5 Test report

The test report for each determination shall include at least the following information:

a) identification of the sample including description;

b) a reference to this document, i. e. ISO/DIS 13402:2023;

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