International Standard

ISO 13402

Second edition
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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*



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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 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.

# 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.

### 4.3 Overview of test methods and applicability

Table 1 enlists several methods for testing. The tests applicable should be chosen according to the materials of the instrument and be performed using the procedure described in respective annex.

When placing an order, the purchaser states 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.

**Table 1 — Overview of test methods and applicability**

| Test method | Applicability | Annex |
|---|---|---|
| Boiling test in deionized water | Martensitic, austenitic, ferritic material with less than 16 % chromium, and precipitation hardening materials shall use the boiling test.<br>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.<br>The boiling test allows to detect surface imperfections, free iron, or other anodic surface contaminations on stainless steel. | Annex A (normative) |
| Boiling test in 0,9 % NaCl solution | Instruments made from stainless steel materials such as austenitic materials, precipitation hardening materials and ferritic materials with a chromium content of 16 % or more should be tested with the boiling test in 0,9 % NaCl. | Annex B (informative) |
| Copper sulfate test for steels with equal or greater than 16 % chromium. | Instruments containing stainless steel materials that are exclusively to the following shall use the copper sulfate test and boiling test: austenitic materials, precipitation hardening materials, and ferritic materials containing equal or greater than 16 % chromium. | Annex C (normative) |
| Copper sulfate test for steels with less than 16 % chromium | Instruments made from martensitic materials with less than 16 % chromium, and precipitation hardening materials to detect improper heat treatment shall be tested with this copper sulfate test. | Annex D (normative) |
| Test in 0,3 % NaCl solution | Instruments made from austenitic steel should be tested with 0,3 % NaCl solution.<br>Corrosion test exclusively for austenitic steels. | Annex E (informative) |
| Test with Citric acid solution | Instruments made from austenitic steel should be tested with citric acid solution.<br>Corrosion test exclusively for austenitic steels. | Annex F (informative) |
| Thermal test | The resistance to thermal stress of instruments made from martensitic or austenitic steel should be tested with the thermal test | Annex G (informative) |
| Autoclave test | Instruments made from martensitic or austenitic steel should be tested with the autoclave test.<br>The sterilization test should simulate normal operating conditions. | Annex H (informative) |

## 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 13402:2025;

c) identification of used method;

d) any unusual features observed during evaluation;

e) any deviations from the procedure;

f) starting and completion dates of test;

g) identification of laboratory carrying out the analysis;

h) signature and name of (an) authorized person(s).

# Annex A
(normative)

# Boiling test in deionized water

## A.1 General

The boiling test is suitable for martensitic, austenitic, ferritic materials with less than 16 % chromium and precipitation hardening materials to detect surface defects, free iron or other anodic surface impurities on stainless steel.

Instruments containing stainless steel materials that are exclusively to the following shall use both the boiling test and copper sulfate test: austenitic materials, precipitation hardening materials, and ferritic materials containing equal or greater than 16 % chromium.

## A.2 Reagents

**A.2.1 Deionized water** according to ISO 3696, quality 3.

## A.3 Apparatus

**A.3.1 Chemically non-reacting vessel**, e.g. made of glass or ceramic, or corrosion resistant stainless steel.

**A.3.2 Energy source** to emit heat (e.g. hob).

**A.3.3 Lint-free disposable cloth.**

**A.3.4 Magnifying lens** (×10).

## A.4 Preparation

Instruments shall be free of oil before test. If necessary, scrub the instrument using soap and warm water. Rinse thoroughly in water (A.2.1) and dry with compressed air or a lint-free disposable cloth.

## A.5 Procedure

Fill vessel (A.3.1) with the required amount of ≥ 2 000 ml of deionized water (A.2.1) for the test and heat to boiling point.

The volume of the saline solution may be adjusted, if more or less solution is needed to fully immerse the instrument.

Place the instrument in the vessel with boiling water for 30 min ± 1 min. The instrument shall be completely covered with water.

Remove the vessel with the instrument from the heat source and allow to cool for 60 min ± 2 min.

Remove the instrument and allow it to react in room air for at least 120 min.

Remove residual moisture with dried compressed air or nitrogen.

## A.6 Evaluation

Direct visual testing shall be done according to EN 13018. Use a magnifying lens (×10) to check for any signs of corrosion on the surface.

Surfaces shall show no signs of corrosion (without magnification). The following exceptions shall not be cause for rejection:

— Rust (ferrous oxide) on serrations, teeth, locks, ratchets inserts, brazed junctions, soldered junctions, etched areas, engravings, or laser marks.

# Annex B
(normative)

# Boiling test in 0,9 % NaCl solution

## B.1 General

The boiling test in 0,9 % NaCl solution is used to determine the corrosion resistance.

## B.2 Reagents

**B.2.1 Deionized water** according to ISO 3696, quality 3.

**B.2.2 Ready-to–use saline solution 0,9 %.**

**B.2.3 Sodium chloride,** NaCl.

Deionized water of quality 3 according to ISO 3696 shall be used for the preparation of the saline solution, and pure sodium chloride shall be used for the analysis.

## B.3 Apparatus

**B.3.1 Chemically non-reacting vessel**, e.g. made of glass or ceramic, or corrosion resistant stainless steel.

**B.3.2 Energy source** to emit heat (e.g. hob).

**B.3.3 Lint-free disposable cloth**.

**B.3.4 Magnifying lens** (×10).

## B.4 Preparation

Weigh 9 g of NaCl (B.2.3) per 1 000 ml of deionized water (B.2.1) with a suitable balance and stir into the deionized water or use ready-to-use isotonic saline solution 0,9 % (B.2.2).

Instruments shall be free of oil before test. If necessary, scrub the instrument using soap and warm water. Rinse thoroughly in water (B.2.1) and dry with compressed air or a lint-free disposable cloth.

## B.5 Test procedure

Fill vessel (B.3.1) with the required amount of ≥ 2 000 ml of saline solution (B.2.2) for the test and heat to boiling point.

The volume of the saline solution may be adjusted, if more or less solution is needed to fully immerse the instrument.

Remove from the energy source and place the prepared test specimens in the solution. Contact time shall be 15 min ± 1 min.

Remove the test specimens from the solution, rinse them in deionized water (B.2.1) and dry them with compressed air.

## B.6 Evaluation

Direct visual testing shall be done according to EN 13018. Use a magnifying lens (×10) to check for any signs of corrosion on the surface.

Surfaces shall show no signs of corrosion (without magnification). The following exceptions shall not be cause for rejection:

— Rust (ferrous oxide) on serrations, teeth, locks, ratchets inserts, brazed junctions, soldered junctions, etched areas, engravings, or laser marks.

# Annex C
(normative)

# Copper sulfate test for steels with equal or greater than 16 % chromium

## C.1 General

This test method provides corrosion test procedures and evaluation methods for steels containing equal or greater than 16 % chromium. The test is an indicator of proper material selection and workmanship by the manufacturer.

Instruments containing stainless steel materials that are exclusively to the following shall use both the copper sulfate test and the boiling test: austenitic materials, precipitation hardening materials, and ferritic materials containing equal or greater than 16 % chromium.

The boiling test and the copper sulfate test shall be used for equipment containing only stainless steel materials: austenitic materials (Class 3), precipitation hardening materials (Class 5) and ferritic materials (Class 6) with a chromium content of 16 % or more.

The copper sulfate test is not recommended for martensitic materials or for ferritic materials with a chromium content of less than 16 %, as these steels can give a positive result regardless of the presence or absence of anodic surface impurities.

## C.2 Reagents

All reagents used shall be of analytical grade.

**C.2.1 Copper sulfate**: crystalline copper sulfate hydrate ($CuSO_4 \cdot 5\ H_2O$), 4 g.

**C.2.2 Sulfuric acid** $H_2SO_4$ ($\varrho$ = 1,84 g/cm$^3$), 1 ml.

**C.2.3 Deionized water** according to ISO 3696, quality 3.

**C.2.4 Isoproanol**, 100 %.

**C.2.5 Ethyl alcohol**, 95 %.

## C.3 Equipment

**C.3.1 Chemically non-reacting vessel**, e.g. made of glass or ceramic, or corrosion resistant stainless steel.

**C.3.2 Magnifying lens** (×10).

## C.4 Preparation

### C.4.1 Sample preparation

Scrub instrument with soap and warm water, rinse thoroughly with water and dry with isopropanol (C.2.4) or 95 % ethyl alcohol (C.2.5).

### C.4.2 Preparation of the copper sulfate solution

Pour 250 ml of deionized water into a chemically non-reactive vessel (C.3.1). Add 5 g of crystalline copper sulfate (C.2.1) and stir until the crystals are completely dissolved. Then add 1,84 g of sulfuric acid (C.2.2) and mix thoroughly.

## C.5 Test procedure

Immerse the instrument at room temperature in the copper sulfate solution contained in a chemically non-reactive vessel.

The volume of the saline solution may be adjusted, if more or less solution is needed to fully immerse the instrument.

Instruments that are too large for full immersion shall be partially immersed in the solution or tested by drops of the solution. The instrument shall be incubated in the copper sulfate solution for 6 min ± 30 s.

Rinse the instrument thoroughly with tap water, rub vigorously with a cloth to remove non-adherent copper sulfate deposits.

## C.6 Requirements

For special requirements, refer to the relevant product standard for specific instruments.

## C.7 Evaluation

Direct visual testing shall be done according to EN 13018. Use a magnifying lens (×10) to check for any signs of corrosion on the surface.

Surfaces shall show no signs of copper plating (without magnification). The following exceptions shall not be cause for rejection:

— Copper plating on serrations, teeth, locks, ratchets inserts, brazed junctions, soldered junctions, etched areas, engravings, or laser marks, or dulling of polished surfaces.

— Copper plating at the periphery of the copper sulfate solution drops caused by concentration of the solution due the evaporation.

# Annex D
(normative)

# Copper sulfate test for martensitic steels with less than 16 % chromium

## D.1 General

This test method provides corrosion test procedures and evaluation methods to be used as an indicator of proper material selection and workmanship by the manufacturer.

Instruments containing stainless steel materials that are exclusively to the following shall use both the copper sulfate test and the boiling test: martensitic steel with less than 16 % chromium.

## D.2 Reagents

All reagents used shall be of analytical grade.

**D.2.1 Copper sulfate**: crystalline copper sulfate hydrate ($CuSO_4 \cdot 5\ H_2O$), 1 g.

**D.2.2 Sulfuric acid** $H_2SO_4$ ($\varrho$ = 1,84 g/cm$^3$), 2,5 g.

**D.2.3 Deionized water** according to ISO 3696, quality 3.

**D.2.4 Isopropanol**, 100 %.

**D.2.5 Ethyl alcohol**, 95 %.

## D.3 Equipment

**D.3.1 Chemically non-reacting vessel**, e.g. made of glass or ceramic, or corrosion resistant stainless steel.

**D.3.2 Magnifying lens** (×10).

## D.4 Preparation

### D.4.1 Sample preparation

Scrub instrument with soap and warm water, rinse thoroughly with water and dry with isopropanol (D.2.4) or 95 % ethyl alcohol (D.2.5).

### D.4.2 Preparation of the copper sulfate solution

Pour 22,5 ml of deionized water into a chemically non-reactive vessel (D.3.1). Add 1 g of crystalline copper sulfate (D.2.1) and stir until the crystals are completely dissolved. Then add 2,5 g of sulfuric acid (D.2.2) and mix thoroughly.

## D.5 Test procedure

Immerse the instrument at room temperature in the copper sulfate solution contained in a chemically non-reactive vessel.

Instruments that are too large for full immersion shall be partially immersed in the solution or tested by drops of the solution. The instrument shall be incubated in the copper sulfate solution for 6 min ± 30 s.

Rinse the instrument thoroughly with tap water, rub vigorously with a cloth to remove non-adherent copper sulfate deposits.

## D.6 Requirements

For special requirements, refer to the relevant product standard for specific instruments.

## D.7 Evaluation

Direct visual testing shall be done according to EN 13018. Use a magnifying lens (×10) to check for any signs of corrosion on the surface.

Surfaces shall show no signs of copper plating (without magnification). The following exceptions shall not be cause for rejection:

— copper plating on serrations, teeth, locks, ratchets inserts, brazed junctions, soldered junctions, etched areas, engravings, or laser marks, or dulling of polished surfaces;

— copper plating at the periphery of the copper sulfate solution drops caused by concentration of the solution due the evaporation.

# Annex E
(informative)

# Test in 0,3 % sodium chloride solution of austenitic steels

## E.1 General

The test in 0,3 % sodium chloride solution only applies to austenitic stainless steels.

## E.2 Reagents

**E.2.1 Deionized water** according to ISO 3696, quality 3.

**E.2.2 Sodium chloride**, NaCl.

For the preparation of 0,5 M NaCl solution use water of quality 3 according to ISO 3696.

**E.2.3 Isopropanol**, 100 %.

**E.2.4 Acetone.**

## E.3 Apparatus

**E.3.1 Chemically non-reacting vessel**, e. g. made of glass or ceramic, or corrosion resistant stainless steel.

**E.3.2 Magnifying lens** (×10).

## E.4 Preparation

The test specimens are soaked in pure acetone or isopropanol and then stored for 10 min in an aqueous alkaline cleaning solution pH > 11 (without enzymes). Apply dosage and temperature according to the manufacturer's instructions for the cleaning agent.

Then rinse the specimens sufficiently with deionized water. Dry with compressed air or a lint-free disposable cloth.

**WARNING — Preparation with acetone or isopropanol may only be carried out in well-ventilated rooms. Observe safety instructions!**

## E.5 Test procedure

a) Immerse half (half immersion) or all (full immersion) of the test specimens in a 0,3 % NaCl solution at 20 °C ± 5 °C for 168 hours.

The volume of the saline solution may be adjusted, if more or less solution is needed to fully immerse the instrument.

NOTE There are two methods: half immersion and full immersion. Half immersion applies to some devices that are too large to be fully immersed.

b) After immersion time remove the test specimens from the solution.

c) Rinse the test specimens sufficiently with deionized water (E.2.1).

## E.6 Evaluation

Direct visual testing shall be done according to EN 13018. Use a magnifying lens (×10) to check for any signs of corrosion on the surface.

Corrosion is divided into four stages:

— Stage a: no signs of corrosion.

— Stage b: slight signs of corrosion, including lock corrosion that has little effect on surface reflectance, or contamination that can be easily removed by cleaning and surface pickling.

— Stage c: visible yellow or black rusty stains appear.

— Stage d: several strength corrosion that cannot be removed by wiping.

The acceptance stages shall be agreed to between the manufacturer and customer.

# Annex F
(informative)

# Test with citric acid solution for austenitic steels

## F.1 General

Applies to austenitic stainless steels only.

## F.2 Reagents

**E.2.1** **Deionized water** according to ISO 3696, quality 3.

**E.2.2** **Citric acid** (chemically pure).

Use deionized water of quality 3 according to ISO 3696 to prepare 100 g/l citric acid solution. The water used for the tests shall be of quality 3 according to ISO 3696.

**E.2.3** **Acetone** ≥ 99 %, or

**E.2.4** **Isopropanol** ≥ 99 %.

## F.3 Apparatus

**E.3.1** **Chemically non-reacting vessel**, e.g. made of glass or ceramic, or corrosion resistant stainless steel.

**E.3.2** **Magnifying lens** (×10).

## F.4 Preparation

The test specimens may be soaked in pure acetone ≥ 99 % or isopropanol ≥ 99 % and then exchanged in an aqueous alkaline cleaning solution (without enzymes) for 10 min. Use temperature according to the manufacturer's instructions for the cleaning agent.

Then rinse the test specimens sufficiently with deionized water (according to ISO 3696).

Dry with compressed air or a lint-free disposable cloth.

**Warning — Preparation with acetone or isopropanol may only be carried out in well-ventilated rooms. Follow safety instructions!**

## F.5 Test procedure

a) Immerse the test specimens in the citric acid solution at room temperature for 5 h ± 10 min;

b) Remove the test specimens and rinse with deionized water;

c) Place in a vessel with boiling water and boil for 30 min ± 3 min at ≥ 93 °C;

d) Allow the specimens to cool in the water and stand in the test solution for 48 h at room temperature;