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
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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).

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

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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.

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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.

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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.

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*

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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.

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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. 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. 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. 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. 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. 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;

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g) identification of laboratory carrying out the analysis;

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

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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).

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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.

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