Surgical and dental hand instruments - Determination of resistance against autoclaving, corrosion and thermal exposure

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EESTI STANDARDI EESSÕNA **NATIONAL FOREWORD**

Käesolev Eesti standard EVS-EN ISO 13402:2001 sisaldab Euroopa standardi EN ISO 13402:2000 ingliskeelset teksti. Käesolev dokument on jõustatud 09.03.2001 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN ISO 13402:2001 consists of the English text of the European standard EN ISO 13402:2000. This document is endorsed on 09.03.2001 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.

Käsitlusala: This standard describes test methods to determine the resistance of stainless steel surgical and dental hand instruments against autoclaving, corrosion and thermal exposure.	**Scope:** This standard describes test methods to determine the resistance of stainless steel surgical and dental hand instruments against autoclaving, corrosion and thermal exposure.

ICS 11.040.30, 11.060.20

Võtmesõnad: autoclaves, corrosion resistance, dental equipment, dental handpieces, dental instruments, medical equipment, surgical equipment, surgical instruments, testing, thermal stability

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 13402

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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 2000-09-09.

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.

The European Standards exist 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, the Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom.

CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

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

Ref. No. EN ISO 13402 : 2000 E

Foreword

International Standard

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

which was prepared by ISO/TC 170 ' Surgical instruments' of the International Organization for Standardization, has been adopted by Technical Committee CEN/TC 55 'Dentistry', the Secretariat of which is held by DIN, as a European Standard.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, and conflicting national standards withdrawn, by April 2001 at the latest.

In accordance with the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard:

Austria, Belgium, the Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom.

Endorsement notice

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

NOTE: Normative references to international publications are listed in Annex ZA (normative).

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.

1 Scope

This International Standard 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 reference

The following standard contains provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the edition indicated was valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent edition of the standard indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

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

3 Autoclave test for corrosion

The autoclave test attempts to simulate the service environment; it is therefore based on recommended methods of sterilization.

3.1 Reagent

The water used for the test shall be of quality 3 in accordance with ISO 3696:1987.

3.2 Apparatus

Autoclave, operating in the non-vacuum mode, capable of being operated at 134° C to 138° C and 0,22 $MN \cdot m^{-2}$.

3.3 Preparation

Scrub the instrument using soap and warm water. Rinse thoroughly in water (3.1) and dry.

3.4 Test procedure

Place the instrument, unwrapped on a tray, into the autoclave. Using the water (3.1) subject the instrument to an autoclaving cycle of $(3\ ^{+0,5}_{0})$ min at 134 °C to 138 °C and 0,22 $MN \cdot m^{-2}$. After the cycle, open the door. Remove the tray and allow the contents to cool to room temperature.

3.5 Evaluation

Refer to the appropriate product standard for specific requirements.