BRITISH STANDARD

BS EN ISO 13402:2001
BS 7891:1997
Incorporating Amendment No.1 to BS 7891:1997 (renumbers the BS as BS EN ISO 13402:2001)

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

The European Standard EN ISO 13402:2000 has the status of a British Standard

ICS 11.040.30; 11.060.20

Committees responsible for this British Standard

The preparation of this British Standard was entrusted to Technical Committee CH/43, Surgical instruments, upon which the following bodies were represented:

British Iron and Steel Producers Association

British Surgical Trades Association

Department of Health

Institute of Sterile Services Management

Medical Sterile Products Association

National Association of Theatre Nurses

Royal College of Nursing

Royal College of Surgeons of Edinburgh

Royal College of Surgeons of England

This British Standard, having been prepared under the direction of the Health and Environment Sector Board, was published under the authority of the Standards Board and comes into effect on 15 March 1997

Amendments issued since publication

Amd. No.	Date	Comments
13008	March 2001	Implementation of the European Standard

The following BSI references relate to the work on this standard:
Committee reference CH/43
Draft for comment 94/503763 DC

ISBN 0 580 26646 X

Contents

National foreword

This British Standard is the official English language version of EN ISO 13402:2000. It is identical with ISO 13402:1995.

The UK participation in its preparation was entrusted to Technical Committee CH/43, Surgical instruments, which has the responsibility to:

— aid enquirers to understand the text;

— present to the responsible international/European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;

— monitor related international and European developments and promulgate them in the UK.

A list of organizations represented on this committee can be obtained on request to its secretary.

Cross-references

Attention is drawn to the fact that CEN and CENELEC Standards normally include an annex which lists normative references to international publications with their corresponding European publications. The British Standards which implement these international or European publications may be found in the BSI Standards Catalogue under the section entitled "International Standards Correspondence Index", or by using the "Find" facility of the BSI Standards Electronic Catalogue.

A British Standard does not purport to include all the necessary provisions of a contract. Users of British Standards are responsible for their correct application.

Compliance with a British Standard does not of itself confer immunity from legal obligations.

Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, the EN ISO title page, the EN ISO foreword page, pages 1 and 4, an inside back cover and a back cover.

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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 la corrosion et à l'exposition à la chaleur (ISO13402:1995)

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

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

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.

NOTE Normative references to International Standards are listed in Annex ZA.

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 °X αvδ 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.

4 Boiling water test for corrosion

The boiling water test is specified for determining corrosion resistance.

4.1 Reagent

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

4.2 Apparatus

Glass or *ceramic beaker* or suitable *corrosion-resistant stainless steel vessel*.