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Responsible committee: W/- Consumer Products and Services Sector Policy and Strategy Committee

Interested committees:

Title: Draft BS EN ISO 13402 ISO 13402 Surgical and dental hand instruments — Determination of resistance against autoclaving, corrosion and thermal exposure.

Please notify the secretary if you are aware of any keywords that might assist in classifying or identifying the standard or if the content of this standard

- i) has any issues related to 3rd party IPR, patent or copyright
- ii) affects other national standard(s)
- iii) requires additional national guidance or information

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This draft is issued to allow comments from interested parties; all comments will be given consideration prior to publication. No acknowledgement will normally be sent. **See overleaf for information on the submission of comments.**

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## Introduction

This draft standard is based on national and international discussions. Your comments on this draft are invited and will assist in the preparation of the consequent standard.

For international standards, comments will be reviewed by the relevant UK national committee before sending the consensus UK vote and comments to the international committee, which will then decide appropriate action. If the international standard is approved, it is usual for the text to be published as a British Standard.

For national standards, comments will be reviewed by the relevant UK national committee and the resulting standards published as a British Standard.

## UK Vote

Please indicate whether you consider the UK should submit a negative (with supporting technical reasons) or positive vote on this draft. Please indicate if you are aware of any reason why this draft standard should not be published as a British Standard.

## Submission of Comments

- **Annotated drafts are not acceptable and will be rejected.**
- All comments should be submitted online at <https://standardsdevelopment.bsigroup.com/>. You will need to register in order to comment.

## Template for comments and secretariat observations

|                  |                        |
|------------------|------------------------|
| Date: xx/xx/20xx | Document: ISO/DIS xxxx |
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| 1  | 2                                          | (3)                          | 4               | 5                                                                                                                                  | (6)                                                                      | 7                                                  |
|----|--------------------------------------------|------------------------------|-----------------|------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------|----------------------------------------------------|
| MB | Clause No./ Subclause No./Annex (e.g. 3.1) | Paragraph/ Figure/Table/Note | Type of comment | Comment (justification for change) by the MB                                                                                       | Proposed change by the MB                                                | Secretariat observations on each comment submitted |
|    | 3.1                                        | Definition 1                 | ed              | Definition is ambiguous and needs clarifying.                                                                                      | Amend to read '...so that the mains connector to which no connection...' |                                                    |
|    | 6.4                                        | Paragraph 2                  | te              | The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK. | Delete reference to UV photometer.                                       |                                                    |

# DRAFT INTERNATIONAL STANDARD

## ISO/DIS 13402

ISO/TC 170

Secretariat: DIN

Voting begins on:  
2023-11-16

Voting terminates on:  
2024-02-08

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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

This document is circulated as received from the committee secretariat.

**ISO/CEN PARALLEL PROCESSING**

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## Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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](http://www.iso.org/directives)).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see [www.iso.org/patents](http://www.iso.org/patents)).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see [www.iso.org/iso/foreword.html](http://www.iso.org/iso/foreword.html).

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:

- 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](http://www.iso.org/members.html).

## 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.