Draft for Public Comment

Form 36

DPC: 25/30491507 DC

BSI Group Headquarters

389 Chiswick High Road London W4 4AL

Tel: +44 (0)20 8996 9000
Fax: +44 (0)20 8996 7400
www.bsigroup.com

Date: 17 January 2025
Origin: International

Latest date for receipt of comments: 12 March 2025

Project No. 2024/01160

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

Interested committees:

Title: Draft BS ISO 6335-2 Surgical instruments — Staplers. Part 2: General requirements.

Please notify admin.start@bsigroup.com if you are aware of any keywords that might assist in clarifying or identifying the standard or of 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

WARNING: THIS IS A DRAFT AND MUST NOT BE REGARDED OR USED AS A BRITISH STANDARD. THIS DRAFT IS NOT CURRENT BEYOND 12 March 2025

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.**

No copying is allowed, in any form, without prior written permission from BSI except as permitted under the Copyright, Designs and Patent Act 1988 or for circulation within a nominating organization for briefing purposes. Electronic circulation is limited to dissemination by e-mail within such an organization by committee members.

Further copies of this draft may be purchased from BSI Shop http://shop.bsigroup.com or from BSI Customer Services, Tel: +44(0) 20 8996 9001 or email cservices@bsigroup.com. British, International and foreign standards are also available from BSI Customer Services.

Information on the co-operating organizations represented on the committees referenced above may be obtained from https://standardsdevelopment.bsigroup.com/.

Documents
Document Sharing Hub

Full document details: 25/30491507 DC

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

1	2	(3)	4	5	(6)	7
MB	Clause No./ Subclause No./Annex **(e.g. 3.1)**	Paragraph/ Figure/Table/Note	**Type of comment**	**Commend (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.	

Documents
Document Sharing Hub

Full document details: 25/30491507 DC

DRAFT International Standard

ISO/DIS 6335-2

Surgical instruments — Staplers —

Part 2: General requirements

ICS: 11.040.30

ISO/TC **170**

Secretariat: **DIN**

Voting begins on:
2025-01-17

Voting terminates on:
2025-04-11

THIS DOCUMENT IS A DRAFT CIRCULATED FOR COMMENTS AND APPROVAL. IT IS THEREFORE SUBJECT TO CHANGE AND MAY NOT BE REFERRED TO AS AN INTERNATIONAL STANDARD UNTIL PUBLISHED AS SUCH.

IN ADDITION TO THEIR EVALUATION AS BEING ACCEPTABLE FOR INDUSTRIAL, TECHNOLOGICAL, COMMERCIAL AND USER PURPOSES, DRAFT INTERNATIONAL STANDARDS MAY ON OCCASION HAVE TO BE CONSIDERED IN THE LIGHT OF THEIR POTENTIAL TO BECOME STANDARDS TO WHICH REFERENCE MAY BE MADE IN NATIONAL REGULATIONS.

RECIPIENTS OF THIS DRAFT ARE INVITED TO SUBMIT, WITH THEIR COMMENTS, NOTIFICATION OF ANY RELEVANT PATENT RIGHTS OF WHICH THEY ARE AWARE AND TO PROVIDE SUPPORTING DOCUMENTATION.

This document is circulated as received from the committee secretariat.

Reference number
ISO/DIS 6335-2:2025(en)

© ISO 2025

Documents
Document Sharing Hub

Full document details: 25/30491507 DC

COPYRIGHT PROTECTED DOCUMENT

© ISO 2025

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Documents
Document Sharing Hub
Full document details: 25/30491507 DC

Contents

Page

Foreword ... **iv**
Introduction ... **v**
1 Scope ... **1**
2 Normative references ... **1**
3 Terms and definitions ... **2**
4 Classification ... **2**
5 Intended performance ... **2**
6 Design attributes ... **2**
7 Materials ... **3**
8 Design evaluation ... **3**
8.1 General ... 3
8.2 Pre-clinical evaluation ... 3
8.3 Clinical evaluation ... 4
8.4 Post-market surveillance ... 4
9 Manufacture ... **4**
10 Sterilization ... **4**
10.1 General ... 4
10.2 Products supplied sterile ... 4
10.3 Sterilization by the user ... 5
10.3.1 Products supplied non-sterile ... 5
10.3.2 Re-sterilization ... 5
10.3.3 Sterilization residues ... 5
11 Packaging ... **5**
11.1 Protection from damage in storage and transportation ... 5
11.2 Maintenance of sterility in transit ... 5
12 Information supplied by the manufacturer ... **5**
12.1 General ... 5
12.2 Labelling ... 6
12.3 Instructions for use ... 6
12.4 Restrictions on combinations ... 7
12.5 Marking for special purposes ... 7
Bibliography ... **8**

© ISO 2025 – All rights reserved

Documents
Document Sharing Hub
Full document details: 25/30491507 DC