



**International
Standard**

ISO 6335-2

**Surgical instruments — Staplers —
Part 2:
General requirements**

Instruments chirurgicaux — Agrafeuses —

Partie 2: Exigences générales

**First edition
2026-02**

iTeh Standards

(<https://standards.iteh.ai>)

Document Preview

ISO 6335-2:2026

<https://standards.iteh.ai/catalog/standards/iso/ec395794-4981-48d7-8441-77a5b4b7ab3c/iso-6335-2-2026>

iTeh Standards
(<https://standards.iteh.ai>)
Document Preview

ISO 6335-2:2026

<https://standards.iteh.ai/catalog/standards/iso/ec395794-4981-48d7-8441-77a5b4b7ab3c/iso-6335-2-2026>



COPYRIGHT PROTECTED DOCUMENT

© ISO 2026

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

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	6
12.1 General	6
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