



SLOVENSKI STANDARD

oSIST prEN ISO 11140-3:2025

01-september-2025

Sterilizacija izdelkov za zdravstveno nego - Kemijski indikatorji - 3. del: Indikatorji tipa 2 za uporabo pri Bowie-Dickovem preskusu prodiranja pare (ISO/DIS 11140-3:2025)

Sterilization of health care products - Chemical indicators - Part 3: Type 2 indicators for use in the Bowie and Dick-type steam penetration test (ISO/DIS 11140-3:2025)

Sterilisation von Produkten für die Gesundheitsfürsorge - Chemische Indikatoren - Teil 3: Indikatorsysteme der Klasse 2 zur Verwendung im Bowie-Dick-Dampfdurchdringungstest (ISO/DIS 11140-3:2025)

Stérilisation des produits de santé - Indicateurs chimiques - Partie 3: Indicateurs de Type 2 pour utilisation lors de l'essai de Bowie et Dick de pénétration de la vapeur (ISO/DIS 11140-3:2025)

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

<https://standards.iteh.ai/catalog/standards/sist/26b10a84-f3c5-424b-acb3-4b6a0a6bc725/osist-pren-iso-11140-3-2025>

Ta slovenski standard je istoveten z: prEN ISO 11140-3

ICS:

11.080.01	Sterilizacija in dezinfekcija na splošno	Sterilization and disinfection in general
-----------	--	---

oSIST prEN ISO 11140-3:2025

en,fr,de



DRAFT International Standard

ISO/DIS 11140-3

Sterilization of health care products — Chemical indicators —

Part 3:

Type 2 indicators for use in the Bowie and Dick-type steam penetration test

Stérilisation des produits de santé — Indicateurs chimiques —

*Partie 3: Indicateurs de Type 2 pour utilisation lors de l'essai de
Bowie et Dick de pénétration de la vapeur*

ICS: 11.080.20

ISO/TC 198

Secretariat: **ANSI**

Voting begins on:
2025-07-29

Voting terminates on:
2025-10-21

This document is circulated as received from the committee secretariat.

ISO/CEN PARALLEL PROCESSING

Reference number
ISO/DIS 11140-3:2025(en)

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.

© ISO 2025

ISO/DIS 11140-3:2025(en)

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

[oSIST prEN ISO 11140-3:2025](https://standards.iteh.ai/catalog/standards/sist/26b10a84-f3c5-424b-acb3-4b6a0a6bc725/osist-pren-iso-11140-3-2025)

<https://standards.iteh.ai/catalog/standards/sist/26b10a84-f3c5-424b-acb3-4b6a0a6bc725/osist-pren-iso-11140-3-2025>



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

ISO/DIS 11140-3:2025(en)

Contents

Page

Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 General	3
5 Requirements	3
6 Indicator format	4
7 Performance requirements	4
8 Packaging and labelling	5
Annex A (normative) Estimation of visual difference between colour of the substrate and of the changed or unchanged indicator system by determination of relative reflectance density	7
Annex B (normative) Determination of uniform colour change on exposure to saturated steam	11
Annex C (normative) Determination of non-uniform colour change on exposure to a reference fault condition	12
Annex D (normative) Reproducibility and determination of the reference fault condition in the standard test pack	14
Annex E (normative) Determination of indicator colour change on exposure to dry heat	18
Annex F (normative) Determination of shelf life of indicators	19
Annex G (normative) Determination of transfer of indicator to standard test pack on processing	20
Annex H (normative) Steam exposure apparatus and steam for test purposes	21
Annex I (normative) Standard test pack	24
Annex J (normative) Air injection system	25
Annex K (informative) Relationship between chemical indicator components	27
Annex ZA (informative) Relationship between this European Standard and the General Safety and Performance Requirements of Regulation (EU) 2017/745 aimed to be covered	28
Bibliography	31