



# SLOVENSKI STANDARD

## oSIST prEN ISO 11140-4:2025

01-september-2025

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**Sterilizacija izdelkov za zdravstveno nego - Kemijski indikatorji - 4. del: Sistemi indikatorjev tipa 2, ki se uporabljajo namesto Bowie-Dickovega preskusa za ugotavljanje prodiranja pare (ISO/DIS 11140-4:2025)**

Sterilization of health care products - Chemical indicators - Part 4: Type 2 indicator systems as an alternative to the Bowie and Dick-type test for the detection of steam penetration (ISO/DIS 11140-4:2025)

Sterilisation von Produkten für die Gesundheitsfürsorge - Chemische Indikatoren - Teil 4: Indikatoren der Klasse 2, die alternativ zum Bowie-Dick-Test für den Nachweis der Dampfdurchdringung verwendet werden (ISO/DIS 11140-4:2025)

Stérilisation des produits de santé - Indicateurs chimiques - Partie 4: Systèmes d'indicateurs de Type 2 comme alternative à l'essai de Bowie et Dick pour la détection de la pénétration de la vapeur (ISO/DIS 11140-4:2025)

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**Ta slovenski standard je istoveten z: prEN ISO 11140-4**

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**ICS:**

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

**oSIST prEN ISO 11140-4:2025**

**en,fr,de**





# DRAFT International Standard

## ISO/DIS 11140-4

### Sterilization of health care products — Chemical indicators —

Part 4:

### Type 2 indicator systems as an alternative to the Bowie and Dick- type test for the detection of steam penetration

*Stérilisation des produits de santé — Indicateurs chimiques —*

*Partie 4: Systèmes d'indicateurs de Type 2 comme alternative à  
l'essai de Bowie et Dick pour la détection de la pénétration de la  
vapeur*

ICS: 11.080.20

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## ISO/DIS 11140-4:2025(en)

## Contents

Page

|  |           |
|--|-----------|
| <b>Foreword</b> .....  | <b>iv</b> |
| <b>Introduction</b> .....  | <b>v</b>  |
| <b>1 Scope</b> .....   | <b>1</b>  |
| <b>2 Normative references</b> .....  | <b>1</b>  |
| <b>3 Terms and definitions</b> .....   | <b>1</b>  |
| <b>4 General</b> .....   | <b>3</b>  |
| <b>5 Requirements</b> .....  | <b>3</b>  |
| <b>6 Indicator format</b> .....  | <b>4</b>  |
| <b>7 Performance requirements</b> .....  | <b>5</b>  |
| <b>8 Packaging and labelling</b> .....   | <b>6</b>  |
| <b>Annex A (normative) Standard test cycles</b> .....  | <b>9</b>  |
| <b>Annex B (normative) Estimation of visual difference between colour of the substrate and of the changed or unchanged indicator system by determination of relative reflectance density</b> ..... | <b>14</b> |
| <b>Annex C (normative) Determination of uniform colour change on exposure to saturated steam</b> .....   | <b>18</b> |
| <b>Annex D (normative) Determination of equivalence of the alternative indicator to the Bowie and Dick test</b> .....  | <b>19</b> |
| <b>Annex E (normative) Determination of reproducibility of fail conditions created in a standard test pack by air injection, air leak and retained air systems</b> .....                           | <b>21</b> |
| <b>Annex F (normative) Determination of indicator colour change on exposure to dry heat</b> .....  | <b>25</b> |
| <b>Annex G (normative) Determination of shelf life of indicators</b> .....   | <b>26</b> |
| <b>Annex H (normative) Steam exposure apparatus and steam for test purposes</b> .....  | <b>27</b> |
| <b>Annex I (normative) Standard test pack</b> .....  | <b>30</b> |
| <b>Annex J (normative) Air injection system</b> .....  | <b>31</b> |
| <b>Annex K (informative) Relationship between chemical indicator components</b> .....  | <b>33</b> |
| <b>Annex ZA (informative) Relationship between this European Standard and the General Safety and Performance Requirements of Regulation (EU) 2017/745 aimed to be covered</b> .....                | <b>34</b> |
| <b>Bibliography</b> .....  | <b>37</b> |

## ISO/DIS 11140-4:2025(en)

## Foreword

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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)).

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This document was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*

This third edition cancels and replaces the second edition (ISO 11140-4:2007), which has been technically revised.

The main changes are as follows:

- change of title from class 2 indicator to type 2 indicator to align with ISO 11140-1;
- correct use of the defined terms indicator and indicator system to align with ISO 11140-1;
- updated normative references;
- inserted common [Clause 4](#) for ISO/TC 198 documents, replacing Clause 8;
- added Annex M, modified from ISO 11140-1.

A list of all parts in the ISO 11140 series can be found on the ISO website.

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