



**SLOVENSKI STANDARD**  
**oSIST prEN ISO 11238:2026**

**01-marec-2026**

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**Zdravstvena informatika - Identifikacija medicinskih izdelkov - Elementi in zgradba podatkov za enotno identifikacijo in izmenjavo predpisanih informacij o substancah (ISO/DIS 11238:2026)**

Health informatics - Identification of medicinal products - Data elements and structures for the unique identification and exchange of regulated information on substances (ISO/DIS 11238:2026)

Medizinische Informatik - Identifikation von Arzneimitteln - Dateielemente und Strukturen zur eindeutigen Identifikation und zum Austausch von vorgeschriebenen Informationen zu Stoffen (ISO/DIS 11238:2026)

Informatique de santé - Identification des produits médicaux - Éléments de données et structures pour l'identification unique et l'échange d'informations réglementées sur les substances (ISO/DIS 11238:2026)

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**Ta slovenski standard je istoveten z: prEN ISO 11238**

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**ICS:**

35.240.80	Uporabniške rešitve IT v zdravstveni tehniki	IT applications in health care technology
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**oSIST prEN ISO 11238:2026**

**en,fr,de**





# DRAFT International Standard

## ISO/DIS 11238

### Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated information on substances

*Informatique de santé — Identification des produits médicaux — Éléments de données et structures pour l'identification unique et l'échange d'informations réglementées sur les substances*

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CH-1214 Vernier, Geneva  
Phone: +41 22 749 01 11  
Email: [copyright@iso.org](mailto:copyright@iso.org)  
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## ISO/DIS 11238:2026(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. [www.iso.org/directives](http://www.iso.org/directives)

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For an explanation on 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 WTO principles in the Technical Barriers to Trade (TBT) see the following URL: [Foreword - Supplementary information](#).

This document was prepared by ISO/TC 215, *Health informatics*.

This third edition cancels and replaces the second edition (ISO 11238:2018), which has been technically revised.

The main changes are correction in the element describing chemical substance type, as well as various adjustment in the document.

To be noted: the section related to Specified Substance Group 4 represented in this document hasn't been updated, and the authors acknowledge that the proposed model would need updates. However, a work item proposal has been adopted and is currently being developed within ISO/TC 215, *Health informatics*, related to the unique identification and exchange of Manufacturing Process & Controls Information of products and substances (ISO/NP 26060). When ready, this document will cancel and replaces the section related to Specified Substance Group 4, in ISO 11238 and ISO/TS 19844 series.

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).