

<b>STN</b>	<b>Zdravotnícka informatika</b> <b>Identifikácia liekov</b> <b>Dátové prvky a štruktúry na jednoznačnú</b> <b>identifikáciu a výmenu regulovaných informácií</b> <b>o lieku (ISO 11615: 2017/Amd 1: 2022)</b> <b>Zmena A1</b>	<b>STN</b> <b>EN ISO 11615/A1</b>  84 8113
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Health informatics - Identification of medicinal products - Data elements and structures for the unique identification and exchange of regulated medicinal product information (ISO 11615:2017)

Táto norma obsahuje anglickú verziu európskej normy.  
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 12/22

Obsahuje: EN ISO 11615:2017/A1:2022, ISO 11615:2017/Amd 1:2022

EUROPEAN STANDARD  
NORME EUROPÉENNE  
EUROPÄISCHE NORM

**EN ISO 11615:2017/A1**

September 2022

ICS 35.240.80

English Version

**Health informatics - Identification of medicinal products -  
Data elements and structures for the unique identification  
and exchange of regulated medicinal product information -  
Amendment 1 (ISO 11615:2017/Amd 1:2022)**

Informatique de santé - Identification des médicaments  
- Éléments de données et structures pour  
l'identification unique et l'échange d'informations sur  
les médicaments contrôlés - Amendement 1 (ISO  
11615:2017/Amd 1:2022)

Medizinische Informatik - Identifikation von  
Arzneimitteln - Datenelemente und Strukturen zur  
eindeutigen Identifikation und zum Austausch von  
vorgeschriebenen Arzneimittelinformationen -  
Änderung 1 (ISO 11615:2017/Amd 1:2022)

This amendment A1 modifies the European Standard EN ISO 11615:2017; it was approved by CEN on 12 August 2022.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for inclusion of this amendment into the relevant national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This amendment exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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EUROPEAN COMMITTEE FOR STANDARDIZATION  
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**CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels**

**EN ISO 11615:2017/A1:2022 (E)**

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## **European foreword**

This document (EN ISO 11615:2017/A1:2022) has been prepared by Technical Committee ISO/TC 215 "Health informatics" in collaboration with Technical Committee CEN/TC 251 "Health informatics" the secretariat of which is held by NEN.

This Amendment to the European Standard EN ISO 11615:2017 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by March 2023, and conflicting national standards shall be withdrawn at the latest by March 2023.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

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## **Endorsement notice**

The text of ISO 11615:2017/Amd 1:2022 has been approved by CEN as EN ISO 11615:2017/A1:2022 without any modification.

# INTERNATIONAL STANDARD

# ISO 11615

Second edition  
2017-10

**AMENDMENT 1**  
**2022-08**

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

### **AMENDMENT 1**

*Informatique de santé — Identification des médicaments — Éléments  
de données et structures pour l'identification unique et l'échange  
d'informations sur les médicaments contrôlés*

*AMENDEMENT 1*



Reference number  
ISO 11615:2017/Amd.1:2022(E)

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## 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 215, *Health informatics*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 251, *Health informatics*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

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).

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