SLOVENSKI STANDARD
SIST EN ISO 11615:2018/oprA1:2021

01-december-2021

Zdravstvena informatika - Identifikacija zdravil - Elementi in zgradba podatkov za enotno identifikacijo in izmenjavo predpisanih informacij o zdravilih - Dopolnilo A1 (ISO 11615:2017/DAM 1:2021)

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/DAM 1:2021)

Medizinische Informatik - Identifikation von Arzneimitteln - Datenelemente und Strukturen zur eindeutigen Identifikation und zum Austausch von vorgeschriebenen Arzneimittelinformationen - Änderung 1 (ISO 11615:2017/DAM 1:2021)

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/DAM 1:2021)

Ta slovenski standard je istoveten z: **EN ISO 11615:2017/prA1**

ICS:

11.120.10	Zdravila	Medicaments
35.240.80	Uporabniške rešitve IT v zdravstveni tehniki	IT applications in health care technology

SIST EN ISO 11615:2018/oprA1:2021 **en,fr,de**

DRAFT AMENDMENT
ISO 11615:2017/DAM 1

ISO/TC **215**
Secretariat: **ANSI**

Voting begins on:
2021-10-14

Voting terminates on:
2022-01-06

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

ICS: 35.240.80

IMPORTANT — Please use this updated version dated 2021-08-18, and discard any previous version of this DAM. The URN has been corrected.

This document is circulated as received from the committee secretariat.

ISO/CEN PARALLEL PROCESSING

Reference number
ISO 11615:2017/DAM 1:2021(E)

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Published in Switzerland

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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).

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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

Introduction, last 2 paragraphs

Remove the last paragraph and add the following text.

Reference to the use of other normative IDMP and messaging standards for Medicinal Product information is included in this document to support successful information exchange.

In addition, Annex C has been included for language translation considerations and preferred terms in support of ISO 11615:2017.

Clause 2, ISO/TS 20443

Footnote added

Annex C provides translations and synonyms utilized in regulatory, clinical, pharmacovigilance, healthcare and by governmental organisations for IDMP class names and attributes defined in ISO 11615:2017 on an international scale.

Annex C

Add the following after Annex B, before the bibliography.