



SLOVENSKI STANDARD SIST-TS CEN ISO/TS 17251:2023

01-maj-2023

Nadomešča:

SIST-TS CEN ISO/TS 17251:2017

Zdravstvena informatika - Poslovne zahteve za sintakso za izmenjavo strukturiranih podatkov o odmerkih za zdravila (ISO/TS 17251:2023)

Health informatics - Business requirements for a syntax to exchange structured dose information for medicinal products (ISO/TS 17251:2023)

Medizinische Informatik - Geschäftsanforderungen an eine Syntax zum Austausch von Dosierungsinformationen für Arzneimittel (ISO/TS 17251:2023)

Informatique de santé - Exigences d'affaire pour une syntaxe d'échange d'informations de dose structurée pour les produits médicaux (ISO/TS 17251:2023)

Ta slovenski standard je istoveten z: CEN ISO/TS 17251:2023

ICS:

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

SIST-TS CEN ISO/TS 17251:2023 **en,fr,de**

TECHNICAL SPECIFICATION
SPÉCIFICATION TECHNIQUE
TECHNISCHE SPEZIFIKATION

CEN ISO/TS 17251

March 2023

ICS 35.240.80

Supersedes CEN ISO/TS 17251:2016

English Version

**Health informatics - Business requirements for a syntax to
exchange structured dose information for medicinal
products (ISO/TS 17251:2023)**

Informatique de santé - Exigences d'affaire pour une
syntaxe d'échange d'informations de dose structurée
pour les produits médicaux (ISO/TS 17251:2023)

Medizinische Informatik - Geschäftsanforderungen an
eine Syntax zum Austausch von
Dosierungsinformationen für Arzneimittel (ISO/TS
17251:2023)

This Technical Specification (CEN/TS) was approved by CEN on 24 February 2023 for provisional application.

The period of validity of this CEN/TS is limited initially to three years. After two years the members of CEN will be requested to submit their comments, particularly on the question whether the CEN/TS can be converted into a European Standard.

CEN members are required to announce the existence of this CEN/TS in the same way as for an EN and to make the CEN/TS available promptly at national level in an appropriate form. It is permissible to keep conflicting national standards in force (in parallel to the CEN/TS) until the final decision about the possible conversion of the CEN/TS into an EN is reached.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Contents	Page
European foreword.....	3

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[SIST-TS CEN ISO/TS 17251:2023](https://standards.iteh.ai/catalog/standards/sist/8bca211a-ffb8-4d4a-a5ff-f45baec62a5c/sist-ts-cen-iso-ts-17251-2023)
<https://standards.iteh.ai/catalog/standards/sist/8bca211a-ffb8-4d4a-a5ff-f45baec62a5c/sist-ts-cen-iso-ts-17251-2023>

European foreword

This document (CEN ISO/TS 17251:2023) 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.

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.

This document supersedes CEN ISO/TS 17251:2016.

Any feedback and questions on this document should be directed to the users' national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to announce this Technical Specification: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

iTeh STANDARD PREVIEW (standards.iteh.ai)

Endorsement notice

The text of ISO/TS 17251:2023 has been approved by CEN as CEN ISO/TS 17251:2023 without any modification.

[SIST-TS CEN ISO/TS 17251:2023](https://standards.iteh.ai/catalog/standards/sist/8bca2111a-ffb8-4d4a-a5ff-f45baec62a5c/sist-ts-cen-iso-ts-17251-2023)

<https://standards.iteh.ai/catalog/standards/sist/8bca2111a-ffb8-4d4a-a5ff-f45baec62a5c/sist-ts-cen-iso-ts-17251-2023>

TECHNICAL
SPECIFICATION

ISO/TS
17251

Second edition
2023-02

**Health informatics — Business
requirements for a syntax to exchange
structured dose information for
medicinal products**

*Informatique de santé — Exigences d'affaire pour une syntaxe
d'échange d'informations de dose structurée pour les produits
médicaux*

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[SIST-TS CEN ISO/TS 17251:2023](https://standards.iteh.ai/catalog/standards/sist/8bca211a-ffb8-4d4a-a5ff-f45baec62a5c/sist-ts-cen-iso-ts-17251-2023)

<https://standards.iteh.ai/catalog/standards/sist/8bca211a-ffb8-4d4a-a5ff-f45baec62a5c/sist-ts-cen-iso-ts-17251-2023>



Reference number
ISO/TS 17251:2023(E)

© ISO 2023

iTeh STANDARD PREVIEW (standards.iteh.ai)

[SIST-TS CEN ISO/TS 17251:2023](https://standards.iteh.ai/catalog/standards/sist/8bca211a-ffb8-4d4a-a5ff-f45baec62a5c/sist-ts-cen-iso-ts-17251-2023)

<https://standards.iteh.ai/catalog/standards/sist/8bca211a-ffb8-4d4a-a5ff-f45baec62a5c/sist-ts-cen-iso-ts-17251-2023>



COPYRIGHT PROTECTED DOCUMENT

© ISO 2023

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

Contents

Page

Foreword	iv
Introduction	vi
1 Scope	1
2 Normative references	1
3 Terms and definitions	2
4 Relationship to other ISO deliverables	4
5 Conformance	5
6 Business requirements for structured dose instructions	5
6.1 General.....	5
6.2 Use cases.....	5
6.3 Elements of a dose instruction.....	5
6.4 Information requirements.....	7
6.4.1 General.....	7
6.4.2 Terminologies and Code Systems.....	7
6.4.3 Information model.....	7
6.4.4 Text representation.....	8
6.4.5 Administration amount.....	8
6.4.6 Route/site of administration.....	9
6.4.7 Timing of dose event(s).....	9
6.4.8 Conditional administration.....	11
6.4.9 Subject of care-specific information.....	11
6.4.10 Ancillary information.....	12
Bibliography	14

[SIST-TS CEN ISO/TS 17251:2023](https://standards.iteh.ai/catalog/standards/sist/8bca211a-ffb8-4d4a-a5ff-f45baec62a5c/sist-ts-cen-iso-ts-17251-2023)

<https://standards.iteh.ai/catalog/standards/sist/8bca211a-ffb8-4d4a-a5ff-f45baec62a5c/sist-ts-cen-iso-ts-17251-2023>

ISO/TS 17251:2023(E)

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of 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 World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

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).

This second edition cancels and replaces the first edition (ISO/TS 17251:2016), which has been technically revised.

The main changes are as follows:

- editorial corrections and clarifications;
- added [Clause 4](#) on the relationship to other standards;
- updated [Clause 3](#);
- [Clause 4](#) includes discussion on the relationship to the IDMP standards and clarifies the use of IDMP terms;
- [Subclause 6.4.9](#): removed height, added optional laboratory observations;
- [Subclause 6.4.5](#) and [6.4.7.1](#) for elements described as a range (e.g. max/min dose, range for interval or frequency) added discussion of 2-term and 3-term representations;
- [Subclause 6.4.1](#): added discussion on complex instructions (e.g. multiple schedules, multiple dose amounts);
- [Subclause 6.4.5](#): clarified language around selection of unit of measurement versus unit of presentation;
- [Subclause 6.4.8](#): clarified that conditional administration is not necessarily the indication for the medication order;

- [Subclause 6.4.9.4](#): added capability to provide date and/or time for subject of care characteristics;
- [Subclause 6.4.4.1](#): added description and conformance for administration method;
- [Subclause 6.4.7.1](#): added the option to have frequency based upon a period of time, such as “2 times over 3 days”.

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.

iTeh STANDARD PREVIEW (standards.iteh.ai)

[SIST-TS CEN ISO/TS 17251:2023](#)

<https://standards.iteh.ai/catalog/standards/sist/8bca211a-ffb8-4d4a-a5ff-f45baec62a5c/sist-ts-cen-iso-ts-17251-2023>