Health informatics - Patient healthcard data - Part 5: Identification data (ISO 21549-5:2023)

EESTI STANDARDIMIS- JA AKREDITEERIMISKESKUS
ESTONIAN CENTRE FOR STANDARDISATION AND ACCREDITATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 21549-5:2023 sisaldab Euroopa standardi EN ISO 21549-5:2023 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 21549-5:2023 consists of the English text of the European standard EN ISO 21549-5:2023.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 08.11.2023.	Date of Availability of the European standard is 08.11.2023.
Standard on kättesaadav Eesti Standardimis-ja Akrediteerimiskeskusest.	The standard is available from the Estonian Centre for Standardisation and Accreditation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

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EUROPEAN STANDARD

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English Version

Health informatics - Patient healthcard data - Part 5: Identification data (ISO 21549-5:2023)

Informatique de santé - Données relatives aux cartes de santé des patients ¿ Partie 5: Données d'identification (ISO 21549-5:2023)

Medizinische Informatik - Patientendaten auf Karten im Gesundheitswesen - Teil 5: Identifikationsdaten (ISO 21549-5:2023)

This European Standard was approved by CEN on 1 October 2023.

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

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European foreword

This document (EN ISO 21549-5:2023) 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.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by May 2024, and conflicting national standards shall be withdrawn at the latest by May 2024.

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 EN ISO 21549-5:2016.

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 implement this European Standard: 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.

Endorsement notice

The text of ISO 21549-5:2023 has been approved by CEN as EN ISO 21549-5:2023 without any modification.

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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 document 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).

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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, *Medical informatics,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This third edition cancels and replaces the second edition (ISO 21549-5:2015), of which it constitutes a minor revision. The changes are as follows:

— normative references have been updated;

— errors have been corrected in Annex A.

A list of all parts in the ISO 21549 series can be found on the ISO website.

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.

Introduction

With a more mobile population, greater healthcare delivery in the community and at patients' homes, together with a growing demand for improved quality of ambulatory care, portable information systems and stores have increasingly been developed and used. Such devices are used for tasks ranging from identification, through portable medical record files, and on to patient-transportable monitoring systems.

The functions of such devices are to carry and to transmit person-identifiable information between themselves and other systems; therefore, during their operational lifetime, they can share information with many technologically different systems which differ greatly in their functions and capabilities.

Healthcare administration increasingly relies upon similar automated identification systems. For instance, prescriptions can be automated and data exchange carried out at a number of sites using patient transportable computer readable devices. Healthcare funding institutions and providers are increasingly involved in cross-region care, where reimbursement can require automated data exchange between dissimilar healthcare systems. Administrative data objects can require linkage to external parties responsible for their own domains which are not within the scope of this document. For instance, cross-border reimbursement of healthcare services are usually regulated by law and intergovernmental agreements which are not subject to standardization.

The advent of remotely accessible databases and support systems has led to the development and use of "Healthcare Person" identification devices that are also able to perform security functions and transmit digital signatures to remote systems via networks.

With the growing use of data cards for practical everyday healthcare delivery, the need has arisen for a standardized data format for interchange.

The person-related data carried by a data card can be categorised in three broad types: identification (of the device itself and the individual to whom the data it carries relates), administrative and clinical. It is important to realize that a given healthcare data card "de facto" contains device data and identification data and can in addition contain administrative, clinical, medication and linkage data.

Device data are defined to include:

— identification of the device itself;

— identification of the functions and functioning capabilities of the device.

Identification data are defined to include unique identification of the device holder (and not information of other persons).

Administrative data can include:

— complementary person(s) related data;

— identification of the funding of healthcare, whether public or private, and their relationships, i.e. insurer(s), contract(s) and policy(ies) or types of benefits;

— identification of other persons as a part of the insurance contract (e.g. a family contract);

— other data (distinguishable from clinical data) that are necessary for the purpose of healthcare delivery.

Clinical data can include:

— items that provide information about health and health events;

— their appraisal and labelling by a healthcare provider;

— related actions planned requested or performed.

Medication data can include:

— a record of medications received or taken by the patient;

— copies of prescriptions including the authority to dispense records of dispensed medication;

— records of medication bought by the patient;

— pointers to other systems that contain information that makes up an electronic prescription and the authority to dispense.

As a data card essentially provides specific answers to definite queries while having at the same time a need to optimize the use of memory by avoiding redundancies, “high level” object modelling technique (OMT) has been applied with respect to the definition of healthcare data card data structures.

This document describes and defines the basic structure of the identification data objects held on healthcare data cards using UML, plain text and Abstract Syntax Notation (ASN.1).

This document does not establish the common objects defined within ISO 21549-2 even though they are referenced and utilized within this document.

Health informatics — Patient healthcard data —

Part 5: Identification data

1 Scope

This document describes and defines the basic structure of the identification data objects held on healthcare data cards, but it does not specify particular data sets for storage on devices.

This document does not apply to the detailed functions and mechanisms of the following services (although its structures can accommodate suitable data objects elsewhere specified):

— security functions and related services that are likely to be specified by users for data cards depending on their specific application, e.g. confidentiality protection, data integrity protection and authentication of persons and devices related to these functions;

— access control services;

— the initialization and issuing process (which begins the operating lifetime of an individual data card, and by which the data card is prepared for the data to be subsequently communicated to it according to this document).

Therefore, this document does not cover:

— physical or logical solutions for the practical functioning of particular types of data card;

— the forms that data take for use outside the data card, or the way in which such data are visibly represented on the data card or elsewhere.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/IEC 5218, *Information technology — Codes for the representation of human sexes*

ISO 21549-1, *Health informatics — Patient healthcard data — Part 1: General structure*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 21549-1 and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
identification data
data that provide for the unique identification of the cardholder to whom the records relate