Health Informatics TC251

NEN Standards Development

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Subject Initial list of CEN Standards and technical specifications with relevance to the EHDS regulation *(February 2026)*

General requirements

- EN ISO/HL7 10781:2023 'Health informatics – HL7 Electronic Health Record-System Functional Model, Release 2.1 (EHR FM)'
- EN IEC 62304:2006 'Medical device software – Software life cycle processes' – *revision in development*
- CEN ISO/TS 82304-2:2021 'Health software – Part 2: Health and wellness apps – Quality and reliability'
- EU Harmonised standards in support of the Medical Device Regulation, including:
  - EN ISO 14971:2019 'Medical devices – Application of risk management to medical devices'
  - EN ISO 13485:2016 'Medical devices – Quality management systems – Requirements for regulatory purposes'

Requirements for interoperability

- EN ISO 27269:2021 'Health informatics – International patient summary' – *revision in development*
- EN ISO 17523:2025 'Health informatics – Requirements for electronic prescriptions'
- CEN ISO/TS 19293:2018 'Requirements for a record of a dispense of a medicinal product' – *revision in development*
- EN ISO 12052:2017 'Health informatics – Digital imaging and communication in medicine (DICOM) including workflow and data management' – *revision in development*
- EN ISO 21860:2020 'Health informatics – Reference standards portfolio (RSP) – Clinical imaging'
- EN ISO 11615:2017 'Health Informatics – Identification of medicinal products – Data elements and structures for the unique identification and exchange of regulated medicinal product information' – *revision in development*

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- EN ISO 11616:2017 ‘Health Informatics – Identification of medicinal products – Data elements and structures for unique identification and exchange of regulated pharmaceutical product information’ – *revision in development*

- EN ISO 11238:2018 ‘Health informatics – Identification of medicinal products – Data elements and structures for the unique identification and exchange of regulated information on substances’ – *revision in development*

- EN ISO 11239:2023 ‘Health informatics – Identification of medicinal products – Data elements and structures for the unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging’

- EN ISO 11240:2012 ‘Health informatics – Identification of medicinal products – Data elements and structures for the unique identification and exchange of units of measurement’

- CEN ISO/TS 5615:2025 ‘Health informatics – Accelerating safe, effective and secure remote connected care and mobile health through standards-based interoperability solutions addressing gaps revealed by pandemics’

- prEN ISO 22532 ‘Health informatics — Identification of medicinal products — Core vocabulary (terms and definitions) for the IDMP Standards’

- FprEN ISO 16791 ‘Health informatics — Requirements for international machine-readable coding of medicinal product package identifiers’

Requirements for security and for logging

- EN ISO 27799:2016 ‘Health informatics – Information security management in health using ISO/IEC 27002’ – *revision in development*

- CEN ISO/TS 14441:2013 ‘Health informatics – Security and privacy requirements of EHR systems for use in conformity assessment’

- EN ISO 25237:2017 ‘Health informatics – Pseudonymization’ – *revision in development*

- ISO/IEC TR 27599:2025 ‘Information technology – Brain-computer interfaces – Use cases’

- EN-ISO 27789:2021 ‘Health informatics – Audit trails for electronic health records’

- EN IEC 81001-5-1:2022 ‘Health software and health IT systems safety, effectiveness and security – Part 5-1: Security – Activities in the product life cycle’

Possible future CEN adoption of ISO/national standards

- NEN 7513:2024 ‘Health informatics - Logging – Recording actions on personal health information’
- NEN 7522:2021 ‘Health informatics – Development and maintenance of standards systems of standards’

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