
Zdravstvena informatika - Farmakovigilanca - Varnostno poročilo za posamezni primer - 2. del: Zahteve za farmacevtsko poročanje za varnostno poročilo za posamezni primer (ICSR) pri uporabi humanih zdravil (ISO 27953-2:2011)

Health informatics - Individual case safety reports (ICSRs) in pharmacovigilance - Part 2: Human pharmaceutical reporting requirements for ICSR (ISO 27953-2:2011)

Medizinische Informatik - Pharmakovigilanz - Einzelfallbericht für unerwünschte Arzneimittelwirkungen - Teil 2: Anforderungen für die Einzelfallberichte (ISO 27953-2:2011)

Informatique de santé - Rapports de sécurité de cas individuel (ICSRs) en pharmacovigilance - Partie 2: Exigences pharmaceutiques humaines à rapporter pour un rapport de sécurité de cas individuel (ICSR) (ISO 27953-2:2011)

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ICS:

35.240.80	Uporabniške rešitve IT v zdravstveni tehniki	IT applications in health care technology
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English Version

**Health informatics - Individual case safety reports (ICSRs) in
pharmacovigilance - Part 2: Human pharmaceutical reporting
requirements for ICSR (ISO 27953-2:2011)**

Informatique de santé - Rapports de sécurité de cas
individuel (ICSRs) en pharmacovigilance - Partie 2:
Exigences pharmaceutiques humaines à rapporter pour un
rapport de sécurité de cas individuel (ICSR) (ISO 27953-
2:2011)

Medizinische Informatik - Pharmakovigilanz -
Einzelfallbericht für unerwünschte Arzneimittelwirkungen -
Teil 2: Anforderungen für die Einzelfallberichte (ISO 27953-
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Foreword

This document (EN ISO 27953-2:2011) 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of an identical text or by endorsement, at the latest by June 2012, and conflicting national standards shall be withdrawn at the latest by June 2012.

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