

**SLOVENSKI STANDARD  
SIST EN ISO 27953-1:2012****01-februar-2012**

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**Zdravstvena informatika - Farmakovigilanca - Varnostno poročilo za posamezni primer - 1. del: Okvir za poročanje o stranskih učinkih (ISO 27953-1:2011)**

Health informatics - Individual case safety reports (ICSRs) in pharmacovigilance - Part 1: Framework for adverse event reporting (ISO 27953-1:2011)

Medizinische Informatik - Pharmakovigilanz - Einzelfallbericht für unerwünschte Arzneimittelwirkungen - Teil 1: Grundstruktur für Berichte über unerwünschte Arzneimittelwirkungen (ISO 27953-1:2011)

Informatique de santé - Rapports de sécurité de cas individuel (ICSRs) en pharmacovigilance - Partie 1: Cadre pour rapporter un événement défavorable (ISO 27953-1:2011)

**Ta slovenski standard je istoveten z: EN ISO 27953-1:2011****ICS:**

35.240.80	Uporabniške rešitve IT v zdravstveni tehniki	IT applications in health care technology
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**SIST EN ISO 27953-1:2012****en**

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EUROPEAN STANDARD  
NORME EUROPÉENNE  
EUROPÄISCHE NORM

**EN ISO 27953-1**

December 2011

ICS 35.240.80

English Version

**Health informatics - Individual case safety reports (ICSRs) in  
pharmacovigilance - Part 1: Framework for adverse event  
reporting (ISO 27953-1:2011)**

Informatique de santé - Rapports de sécurité de cas  
individuel (ICSRs) en pharmacovigilance - Partie 1: Cadre  
pour rapporter un événement défavorable (ISO 27953-  
1:2011)

Medizinische Informatik - Pharmakovigilanz -  
Einzelfallbericht für unerwünschte Arzneimittelwirkungen -  
Teil 1: Grundstruktur für Berichte über unerwünschte  
Arzneimittelwirkungen (ISO 27953-1:2011)

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## Foreword

This document (EN ISO 27953-1:2011) 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of an identical text or by endorsement, at the latest by June 2012, and conflicting national standards shall be withdrawn at the latest by June 2012.

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**Health informatics — Individual case  
safety reports (ICSRs) in  
pharmacovigilance —**

**Part 1:  
Framework for adverse event reporting**

**iTeh STANDARD PREVIEW**  
*Informatique de santé — Rapports de sécurité de cas individuel  
(ICSRs) en pharmacovigilance —  
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