

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

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NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 27953-2:2011 sisaldab Euroopa standardi EN ISO 27953-2:2011 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 27953-2:2011 consists of the English text of the European standard EN ISO 27953-2:2011.
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.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 01.12.2011.	Date of Availability of the European standard is 01.12.2011.
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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 27953-2:2011)

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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of an identical text or by endorsement, at the latest by June 2012, and conflicting national standards shall be withdrawn at the latest by June 2012.

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The text of ISO 27953-2:2011 has been approved by CEN as a EN ISO 27953-2:2011 without any modification.