



SLOVENSKI STANDARD SIST EN ISO 17351:2014

01-oktober-2014

Nadomešča:
SIST EN 15823:2010

Embalaža - Braillova pisava na embalaži za zdravila (ISO 17351:2013)

Packaging - Braille on packaging for medicinal products (ISO 17351:2013)

Verpackung - Blindenschrift auf Arzneimittelverpackungen (ISO 17351:2013)

Emballage - Braille sur les emballages destinés aux médicaments (ISO 17351:2013)
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Ta slovenski standard je istoveten z: EN ISO 17351:2014

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ICS:

11.180.30	Pripomočki in prilagoditve za branje	Aids and adaptations for reading
55.020	Pakiranje in distribucija blaga na splošno	Packaging and distribution of goods in general

SIST EN ISO 17351:2014

en

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 17351

July 2014

ICS 55.020

Supersedes EN 15823:2010

English Version

**Packaging - Braille on packaging for medicinal products (ISO
17351:2013)**

Emballage - Braille sur les emballages destinés aux
médicaments (ISO 17351:2013)

Verpackung - Blindenschrift auf Arzneimittelverpackungen
(ISO 17351:2013)

This European Standard was approved by CEN on 10 July 2014.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

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

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

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Foreword

The text of ISO 17351:2013 has been prepared by Technical Committee ISO/TC 122 "Packaging" of the International Organization for Standardization (ISO) and has been taken over as EN ISO 17351:2014 by Technical Committee CEN/TC 261 "Packaging" the secretariat of which is held by AFNOR.

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 January 2015, and conflicting national standards shall be withdrawn at the latest by January 2015.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN 15823:2010.

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, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 17351:2013 has been approved by CEN as EN ISO 17351:2014 without any modification.

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INTERNATIONAL
STANDARD

ISO
17351

First edition
2013-01-15

**Packaging — Braille on packaging for
medicinal products**

Emballage — Braille sur les emballages destinés aux médicaments

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ISO 17351:2013(E)**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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 17351 was prepared by Technical Committee ISO/TC 122, *Packaging*.

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Introduction

This International Standard has been developed to meet various national and regional requirements for Braille on packaging for medicinal products, and technical constraints and user requirements, to harmonize technical standardization and specifications. The knowledge and experience that has been gained in EN 15823:2010 was used for the development of this International Standard.

The background for the creation of an European Standard for Braille on packaging for medicinal products (EN 15823) was a European Directive issued in 2004 by the European Commission (Council Directive 2004/27/EC). This Directive requires Braille labelling on outer packaging for medicinal products within the European Union. In practice it means that basically the name of the medicinal product and, where required, the form and strength has to be in Braille as an aid to identification for blind and partially sighted people.

Braille will continue to be an essential means of communication for blind and visually impaired people around the world. Once other accessible packaging technologies emerge additional standards may be created to complement this International Standard.

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