ICS 55.020 SLOVENSKÁ TECHNICKÁ NORMA Február 2015

STN	**Obaly. Braillovo písmo na obaloch liečivých produktov (ISO 17351: 2013).**	**STN EN ISO 17351** 77 3046

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

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 01/15

Obsahuje: EN ISO 17351:2014, ISO 17351:2013

Oznámením tejto normy sa ruší
STN EN 15823 (77 4002) z novembra 2010

119985

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.

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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of an identical text or by endorsement, at the latest by January 2015, and conflicting national standards shall be withdrawn at the latest by January 2015.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.

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Endorsement notice

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

INTERNATIONAL STANDARD

ISO 17351

First edition
2013-01-15

Packaging — Braille on packaging for medicinal products

Emballage — Braille sur les emballages destinés aux médicaments

Reference number
ISO 17351:2013(E)

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Published in Switzerland

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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.

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

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.

INTERNATIONAL STANDARD **ISO 17351:2013(E)**

Packaging — Braille on packaging for medicinal products

1 Scope

This International Standard specifies requirements and provides guidance for the application of Braille to the labelling of medicinal products.

NOTE The principles in this International Standard can be applied in other sectors, as appropriate.