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

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

## EESTI STANDARDI EESSÕNA

## NATIONAL FOREWORD

| | |
|---|---|
| See Eesti standard EVS-EN ISO 17351:2014 sisaldab Euroopa standardi EN ISO 17351:2014 inglisekeelset teksti. | This Estonian standard EVS-EN ISO 17351:2014 consists of the English text of the European standard EN ISO 17351:2014. |
| 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 16.07.2014. | Date of Availability of the European standard is 16.07.2014. |
| Standard on kättesaadav Eesti Standardikeskusest. | The standard is available from the Estonian Centre for Standardisation. |



Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 55.020

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.



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

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



Ref. No. EN ISO 17351:2014 E

# 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.

# Contents

Page

# 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.

# 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.

## 2 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

**2.1**
**Braille**
tactile reading and writing system composed of Braille cells

**2.2**
**Braille cell**
series of up to six raised dots set out in a domino-type cell

**2.3**
**burst-through**
cracking, breaking, pin-holing of the coating or material surface, visible to the naked eye, caused by the process of embossing Braille

**2.4**
**labelling**
information on the immediate or outer packaging

**2.5**
**Marburg Medium spacing convention**
defined system of dimensions within and between the Braille cells

Note 1 to entry: The Marburg Medium spacing convention for Braille [4] is recommended in the European Commission Guidance [3] for use for medicinal product labelling and is explained in B.3.

**2.6**
**marketing authorization holder**
**MAH**
natural or legal person or entity responsible for placing the medicinal product on the market

## 3 General requirements for medicinal product packaging

### 3.1 Product identification

#### 3.1.1 Information in Braille

The approved Braille text on the labelling shall include the information in Braille as required in the country in which the product is to be supplied.