SLOVENSKI STANDARD
SIST EN ISO 15378:2018/A1:2024

01-november-2024

Primarni embalažni materiali za zdravila - Posebne zahteve za uporabo ISO 9001:2015 v povezavi z dobro proizvodno prakso (DPP) - Dopolnilo 1: Upoštevanje podnebnih sprememb (ISO 15378:2017/Amd 1:2024)

Primary packaging materials for medicinal products - Particular requirements for the application of ISO 9001:2015, with reference to good manufacturing practice (GMP) - Amendment 1: Climate action changes (ISO 15378:2017/Amd 1:2024)

Primärpackmittel für Arzneimittel - Besondere Anforderungen für die Anwendung von ISO 9001:2015 entsprechend der Guten Herstellungspraxis (GMP) - Änderung 1: Ergänzung zu klimabezogenen Maßnahmen (ISO 15378:2017/Amd 1:2024)

Articles d'emballage primaire pour médicaments - Exigences particulières pour l'application de l'ISO 9001:2015 prenant en considération les Bonnes Pratiques de Fabrication (BPF) - Amendement 1: Actions relatives aux changements climatiques (ISO 15378:2017/Amd 1:2024)

Ta slovenski standard je istoveten z: **EN ISO 15378:2017/A1:2024**

ICS:

03.120.10	Vodenje in zagotavljanje kakovosti	Quality management and quality assurance
11.040.01	Medicinska oprema na splošno	Medical equipment in general
55.020	Pakiranje in distribucija blaga na splošno	Packaging and distribution of goods in general

SIST EN ISO 15378:2018/A1:2024 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 15378:2017/A1

September 2024

ICS 03.100.70; 11.040.01

English Version

Primary packaging materials for medicinal products - Particular requirements for the application of ISO 9001:2015, with reference to good manufacturing practice (GMP) - Amendment 1: Climate action changes (ISO 15378:2017/Amd 1:2024)

Articles d'emballage primaire pour médicaments - Exigences particulières pour l'application de l'ISO 9001:2015 prenant en considération les Bonnes Pratiques de Fabrication (BPF) - Amendement 1: Actions relatives aux changements climatiques (ISO 15378:2017/Amd 1:2024)

Primärpackmittel für Arzneimittel - Besondere Anforderungen für die Anwendung von ISO 9001:2015 entsprechend der Guten Herstellungspraxis (GMP) - Änderung 1: Ergänzung zu klimabezogenen Maßnahmen (ISO 15378:2017/Amd 1:2024)

This amendment A1 modifies the European Standard EN ISO 15378:2017; it was approved by CEN on 2 September 2024.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for inclusion of this amendment into the relevant 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 amendment 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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and United Kingdom.

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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Ref. No. EN ISO 15378:2017/A1:2024 E

Contents

Page

European foreword

The text of ISO 15378:2017/Amd 1:2024 has been prepared by Technical Committee ISO/TC 76 "Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use" of the International Organization for Standardization (ISO) and has been taken over as EN ISO 15378:2017/A1:2024 by CCMC.

This Amendment to the European Standard EN ISO 15378:2017 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by March 2025, and conflicting national standards shall be withdrawn at the latest by March 2025.

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

Any feedback and questions on this document should be directed to the users' national standards body. A complete listing of these bodies can be found on the CEN website.

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

Endorsement notice

The text of ISO 15378:2017/Amd 1:2024 has been approved by CEN as EN ISO 15378:2017/A1:2024 without any modification.