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)

EESTI STANDARDIMIS- JA AKREDITEERIMISKESKUS
ESTONIAN CENTRE FOR STANDARDISATION AND ACCREDITATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 15378:2017/A1:2024 sisaldab Euroopa standardi EN ISO 15378:2017/A1:2024 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 15378:2017/A1:2024 consists of the English text of the European standard EN ISO 15378:2017/A1:2024.
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 and Accreditation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 11.09.2024.	Date of Availability of the European standard is 11.09.2024.
Standard on kättesaadav Eesti Standardimis-ja Akrediteerimiskeskusest.	The standard is available from the Estonian Centre for Standardisation and Accreditation.

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

ICS 03.100.70

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

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.

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

4.1

Add the following sentence at the end of the subclause:

The organization shall determine whether climate change is a relevant issue.

4.2

Add the following note at the end of the subclause:

NOTE Relevant interested parties can have requirements related to climate change.

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