

STN	Primárne baliace materiály na liečivé produkty Osobitné požiadavky na používanie normy ISO 9001: 2015 s ohľadom na dobrú výrobnú prax (DVP) Zmena A1: Opatrenia súvisiace so zmenou klímy (ISO 15378: 2017/Amd 1: 2024)	STN EN ISO 15378/A1 01 0335
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Primary packaging materials for medicinal products - Particular requirements for the application of ISO 9001:2015, with reference to good manufacturing practice (GMP) (ISO 15378:2017)

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. 11/24

Obsahuje: EN ISO 15378:2017/A1:2024, ISO 15378:2017/Amd 1:2024

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EUROPEAN STANDARD

EN ISO 15378:2017/A1

NORME EUROPÉENNE

EUROPÄISCHE NORM

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.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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EN ISO 15378:2017/A1:2024 (E)

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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.

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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.



International Standard

ISO 15378

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

*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

**Fourth edition
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**AMENDMENT 1
2024-02**

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ISO 15378:2017/Amd.1:2024(en)**Foreword**

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