

**SLOVENSKI STANDARD**  
**SIST EN ISO 15378:2018/oprA1:2024**  
**01-maj-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/prA1**

**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/oprA1:2024 en**





# 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  
2017-09**

**AMENDMENT 1  
2024-02**