



**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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# **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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