

## საქართველოს სტანდარტი

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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)**

*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)*





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## Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see [www.iso.org/directives](http://www.iso.org/directives)).

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This document was prepared by ISO/TC 76, *Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use*.

This fourth edition cancels and replaces the third edition (ISO 15378:2015), which has been technically revised. The main technical and editorial changes comprise:

- the integration of the sector-specific requirements on quality management systems for medicinal products into ISO 9001:2015;
- the deletion of the requirements on quality manual;
- the inclusion of all annexes of ISO 9001:2015 into this document;
- adjustments to the terminology of ISO 9000:2015, where relevant;
- the inclusion of an alphabetical index of defined terms used in this document.