
**Aseptic processing of health care
products —**

**Part 6:
Isolator systems**

Traitement aseptique des produits de santé —

Partie 6: Systèmes isolateurs

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This document was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

This second edition cancels and replaces the first edition (ISO 13408-6:2005), which has been technically revised. It also incorporates the Amendment ISO 13408-6:2005/Amd.1:2013. The main changes compared to the previous edition are as follows:

- changes to the Introduction;
- changes to the Scope;
- addition of the new Clause 5 "Basic principle of Isolator system";
- addition of risk management approach in Clause 6 "Isolator system specification";
- addition of new informative [Annex A](#) "Devices acting as transfer ports for portable and mobile equipment";
- addition of new informative [Annex B](#) "Isolator system – Explanation of terms used and flow of air and material";
- addition of new informative [Annex C](#) "Isolator system – Direct/indirect product contact surfaces "

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