

ISO 8637-3:2024 Versus ISO 8637-3:2018

Based on the clause-by-clause comparison between ISO 8637-3:2024 and ISO 8637-3:2018, the 2024 edition introduces several substantive changes affecting design verification, performance validation, labelling, and technical documentation. The major gaps requiring action are summarized below, with the applicable parameters highlighted for implementation.

1. Biological Safety, Sterility, and Pyrogenicity

The 2024 edition separates these into distinct clauses. Manufacturers must now maintain objective evidence for:

- Biological evaluation per ISO 10993
- Sterility validation per ISO 11737-2
- Non-pyrogenicity verification

Biological Safety Requirements

