

ISO 1135-5:2025 and ISO 1135-5:2015

GAP Assessment – Consolidated Conclusion Summary (Inline)

Based on the clause-by-clause comparison between ISO 1135-5:2025 and ISO 1135-5:2015, the 2025 edition introduces several substantive changes affecting design verification, performance validation, sterility safeguards, connector standards, and risk documentation. The major gaps requiring action are summarized below, with the applicable parameters highlighted for implementation.

1. Sterility and Protective Caps

- 2025 expands protective cap requirements to cover contamination, stick injury prevention, and packaging protection.
- Shift from “maintain sterility” [2015] to mandatory “shall cover surfaces.” Action: Update DHF inputs and labelling to reflect expanded sterility and safety functions.

Protective Cap Requirements Comparison		
	15 2015	5 2025
Focus	Maintain sterility	Contamination, stick injury, packaging
Requirement	Maintain sterility	Shall cover surfaces
Action	None	Update DHF inputs and labelling