DHF Impact and Actions Recommendation – ISO 1135-5:2025

Gap Assessment: ISO 1135-5:2015 versus ISO 1135-5:2025

Document Type: Design History File (DHF) Impact Analysis

Standard Reference: ISO 1135-5:2025 – Transfusion equipment for medical use – Part 5: Transfusion sets for single use with pressure infusion apparatus

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Revision: 01

1. Executive Summary

ISO 1135-5:2025 introduces several substantive changes compared with the 2015 edition, especially in design verification, performance validation, sterility safeguards, connector standards, chemical and biological evaluation structure, packaging alignment, and risk documentation. The attached gap assessment concludes that organizations should prioritize revalidation of closure-piercing devices, injection sites, flow regulators, connector compliance, and associated technical documentation to achieve alignment with the 2025 edition.

Key Impact Areas for DHF:

- Revised physical and chemical test structure through new Annex alignment.
- Stricter or newly mandatory performance criteria for closure-piercing devices, drip chamber priming, flow regulators, injection sites, and disposal information.
- Mandatory connector transition from ISO 594 references to ISO 80369-7 and ISO 80369-20.
- New post-occlusion bolus volume risk evaluation and user communication requirements.
- Stronger biological evaluation, packaging, labelling, and IFU expectations.

This document maps the major gaps into DHF actions using the same impact-and-actions structure reflected in the attached ISO 8637-2 DHF template.[cite:2]

2. Key Changes Summary

2.1 Reorganized physical and chemical requirement structure

Change: ISO 1135-5:2025 introduces a more structured clause architecture, including new Clause 6 for physical requirements with Annex A as the primary physical test reference, and new Clause 7 for chemical requirements tied to Annex B. This centralizes testing structure and clarifies how conformity evidence should be organized.

DHF Impact:

- Existing verification plans and reports must be remapped to the new clause and annex structure.
- Legacy protocol references to 2015 clause/annex numbering may no longer be sufficient for compliance evidence.
- The DHF should clearly show traceability from each physical and chemical requirement to the updated 2025 test method references.

Recommended Actions:

Action	Timeline	Owner	Priority
Update standards matrix and DHF index to ISO 1135-5:2025 clause/annex structure	2 weeks	Regulatory Affairs	Critical
Revise V&V master plan to map all tests to Annex A and Annex B references	4 weeks	Test Engineering	Critical
Crosswalk legacy 2015 reports to 2025 clauses and identify retest gaps	4 weeks	Quality/Regulatory	High

2.2 Leakage and physical test method updates

Change: The leakage requirement remains functionally the same, but the 2025 edition shifts the test reference from Annex A.2 to Annex A.3 and adds conditioning, degassed water, and extended pressure/time conditions. Although the acceptance criterion is unchanged, the gap assessment states that DHF revalidation is needed because the method itself has changed.

DHF Impact:

- Existing leakage validation data may not be directly sufficient if conducted only to the 2015 method.
- Test protocols and reports must document the revised conditioning and execution requirements.
- Product equivalence arguments should be risk-based and formally justified if full retesting is not immediately performed.

Recommended Actions:

Action	Timeline	Owner	Priority

Update leakage protocol to Annex A.3 conditions	3 weeks	Test Engineering	Critical
Perform gap review of existing leakage evidence against revised method details	3 weeks	Quality/Test Engineering	High
Revalidate leakage performance where legacy evidence does not fully cover the 2025 method	6 weeks	Test Engineering	High

2.3 Closure-piercing device requirements

Change: Several closure-piercing device requirements are retained, but 2025 makes non-coring performance mandatory rather than advisory and updates blood bag port references from ISO 3826-1:2013 to ISO 3826-1:2019 for pull-out and leakage verification. This change affects both design inputs and verification expectations.

DHF Impact:

- Design inputs must explicitly state "no coring shall occur" as a verification requirement.
- Verification must confirm compatibility with blood bag ports per ISO 3826-1:2019 rather than older references.
- Supplier specifications, drawings, and component validation records may need revision to show alignment with updated port standards.

Recommended Actions:

Action	Timeline	Owner	Priority
Update design inputs to include mandatory non-coring acceptance criteria	2 weeks	Design Engineering	Critical
Revise verification protocols for pull-out and leak testing against ISO 3826-1:2019 ports	4 weeks	Test Engineering	Critical
Review closure-piercing device supplier specs and component drawings for 2019 compatibility	4 weeks	Procurement/Design Engineering	High
Conduct revalidation of coring, pull retention, and leak integrity where evidence is outdated	8 weeks	Test Engineering	High

2.4 Filter, drip chamber, and flow regulator performance

Change: The filter clause moves to a new test reference and adds provision for human blood substitutes in some circumstances, while drip chamber priming changes from "should" to "shall," and two flow

regulator expectations become mandatory in 2025. These changes convert previously recommended functionality into explicit compliance obligations.

DHF Impact:

- Verification plans must treat drip chamber priming and flow-regulator durability/material compatibility as mandatory performance attributes.
- Test methods may need updates to incorporate substitute test media where relevant and justified.
- Usability and performance documentation should show that regulator use does not damage tubing and that priming is consistently achievable.

Recommended Actions:

Action	Timeline	Owner	Priority
Update design requirements for drip chamber priming and flow-regulator mandatory criteria	3 weeks	Design Engineering	High
Revise filter and regulator verification protocols to reflect 2025 references and mandatory language	5 weeks	Test Engineering	High
Add tubing damage and storage interaction evidence to regulator validation package	6 weeks	Quality/Test Engineering	High
Review usability evidence for priming performance and clinician handling	6 weeks	Human Factors/QA	Medium

2.5 Injection site requirements

Change: ISO 1135-5:2025 significantly strengthens injection site requirements by requiring zero liquid leakage instead of the 2015 allowance of up to one drop of water, adding mandatory 200 kPa pressure testing for needle-free or Luer-activated sites, and changing preferred placement near the male fitting into a mandatory expectation.

DHF Impact:

- Injection site design verification must be upgraded because the acceptance criteria are stricter.
- Needle-free and Luer-activated injection site variants require explicit pressure integrity evidence at 200 kPa.
- Design outputs and IFU may need revision if the injection site location or functional claims are not clearly aligned with 2025 language.

Recommended Actions: