DHF Impact and Actions Recommendation – ISO 8637-3:2024

Gap Assessment: ISO 8637-3:2024 versus ISO 8637-3:2018

Document Type: Design History File (DHF) Impact Analysis

Standard Reference: ISO 8637-3:2024 – Extracorporeal systems for blood purification – Part 3: Plasmafilters

Date: June 28, 2026

Revision: 01

1. Executive Summary

ISO 8637-3:2024 introduces substantive changes for plasmafilters that affect design verification, performance characterization, connector validation, haemolysis evaluation, labelling, and technical documentation. The attached gap assessment identifies the most significant DHF impacts as the separation of biological safety/sterility/non-pyrogenicity into distinct evidence streams, revised structural-integrity verification, new risk-based connector functionality requirements, expanded performance characterization, haemolytic testing, and stronger test-method governance tied to representative production samples and updated documentation practices.

Key Impact Areas for DHF:

- Separate DHF evidence for biological evaluation, sterility, and non-pyrogenicity.
- Updated structural-integrity and blood-compartment integrity verification logic.
- Expanded connector verification from dimensional fit to risk-based functional performance.
- New or revised plasma filtration, sieving, pressure-drop, and blood-volume evidence expectations.
- New haemolytic characteristics requirement and expiry-date linkage.
- Updated labelling, IFU, packaging, and technical-file traceability.

This document translates the attached ISO 8637-3:2024 versus 2018 comparison into a DHF impact-and-actions plan using the same implementation style as the attached DHF reference document.

2. Key Changes Summary

2.1 Biological evaluation, sterility, and non-pyrogenicity become explicit evidence streams

Change: ISO 8637-3:2024 splits the former combined biological-safety/biocompatibility structure into separate clauses for biological evaluation, sterility, and non-pyrogenicity. The comparison summary states that manufacturers now need objective evidence for biological evaluation per ISO 10993, sterility validation per ISO 11737-2, and non-pyrogenicity verification as distinct compliance elements.

DHF Impact:

- DHF structure should separate biological evaluation, sterility, and pyrogenicity evidence instead of relying on a single combined compliance narrative.
- Traceability matrices, verification summaries, and technical documentation should map each of these evidence streams to its corresponding clause and label claim.
- Existing files may still be scientifically valid, but document organization and cross-references likely need revision.

Recommended Actions:

Action	Timeline	Owner	Priority
Create separate DHF traceability entries for biological evaluation, sterility, and non-pyrogenicity	3 weeks	Regulatory / Quality	Critical
Confirm biological evidence aligns to ISO 10993-based evaluation strategy	4 weeks	Biological Safety	High
Confirm sterility validation records explicitly align to ISO 11737-2	4 weeks	Sterilization / Quality	High
Update pyrogenicity verification rationale and supporting records	4 weeks	Regulatory / Quality	High

2.2 Structural integrity verification becomes more defined and shifts pressure expectations

Change: Structural integrity testing in 2024 uses degassed water at 37 ± 1°C, keeps the positive-pressure requirement at 1.5 times maximum rated pressure, and reduces the negative-pressure limit from 93.3 kPa (700 mmHg) to 66.7 kPa (500 mmHg) with a 10-minute test duration. The gap assessment treats this as a substantive verification update requiring protocol revision.

DHF Impact:

- Structural integrity SOPs, protocols, and reports must be updated to the current test medium, temperature, pressure limits, and hold duration.
- Legacy test evidence may be technically conservative in some respects, but it should be reviewed for explicit alignment to the 2024 method before reuse in the DHF.
- Risk and specification records should no longer cite the older 700 mmHg negative-pressure criterion as the governing standard requirement.

Recommended Actions:

Action	Timeline	Owner	Priority
Revise structural-integrity protocol to degassed water at 37 ± 1°C with 500 mmHg negative-pressure cap	3 weeks	Test Engineering	Critical
Review historical structural-integrity reports for method-alignment gaps	4 weeks	Quality / Test Engineering	High
Update design specifications and risk documents to current pressure criteria	4 weeks	Design Engineering / Risk Manager	High

2.3 Blood compartment integrity shifts from prescriptive method to validation-based evidence

Change: The 2024 edition retains the requirement that the blood compartment shall not leak at 1.5 times maximum transmembrane pressure, but it replaces the older prescriptive bubble-point style test description with verification by manufacturer-validated records review. This is a major DHF shift from direct method prescription to validated procedure evidence.

DHF Impact:

- The DHF must clearly contain validated test-procedure records and approval evidence supporting blood-compartment integrity.
- Document control and validation governance become more important because compliance is demonstrated through records review rather than only by repeating a fixed procedural text.
- Reviewers should be able to trace the pressure criterion, method validation, and no-leak acceptance decision in a controlled manner.

Recommended Actions:

Action	Timeline	Owner	Priority
Validate and formally approve the blood-compartment integrity procedure under DHF control	4 weeks	Test Engineering / Quality	Critical
Create a records-review checklist linking protocol validation, execution, and acceptance evidence	3 weeks	Quality Assurance	High
Assess whether legacy reports need addenda to support the 2024 validation-based approach	4 weeks	QA / Regulatory	High

2.4 Connector requirements expand from dimensions to risk-based functional performance

Change: Connector requirements in 2024 expand from largely dimensional checks to risk-based functional verification, including leakage limits, separation forces, connection/disconnection torque, and more detailed inspection methods for both blood-compartment and plasma-filtrate connectors. The comparison highlights a specific increase in non-locking filtrate connector retention force from 15 N to 25 N for 15 seconds, and references more advanced dimensional verification methods plus ISO 80369-20-based functional testing.

DHF Impact:

- Connector design inputs, drawings, supplier specifications, and inspection methods must be revised to the updated figures, tables, and functional criteria.
- Risk management files need explicit connector leakage, separation, torque, and misconnection acceptance criteria, with boundary conditions defined through the risk process.
- Verification plans and supplier qualification packages will likely require partial revalidation and metrology upgrades.

Recommended Actions:

Action	Timeline	Owner	Priority
Update connector drawings/specifications to 2024 dimensional and interface requirements	4 weeks	Design Engineering	Critical
Define risk-based leakage, force, and torque acceptance criteria in the risk file	5 weeks	Risk Manager / Design Engineering	Critical
Upgrade or validate connector metrology methods, gauges, and test work instructions	6 weeks	Metrology / Test Engineering	High