DHF Impact and Actions Recommendation – ISO 8637-1:2024

Gap Assessment: ISO 8637-1:2024 versus ISO 8637-1:2017

Document Type: Design History File (DHF) Impact Analysis

Standard Reference: ISO 8637-1:2024 – Extracorporeal systems for blood purification – Part 1: Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators

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1. Executive Summary

ISO 8637-1:2024 remains broadly aligned with ISO 8637-1:2017, so many core biological, sterility, blood-compartment integrity, and core performance expectations remain acceptable in principle under existing device designs. The attached gap assessment identifies the main DHF impacts as tighter connector and mechanical verification, new performance requirements for ultrafiltration rate and endotoxin transfer, stronger linkage between sterility/non-pyrogenicity claims and labelling, risk-based sample sizing, final-production test representativeness, and more explicit shelf-life validation expectations.

Key Impact Areas for DHF:

- Label claim traceability for sterility and non-pyrogenicity statements.
- Revised external casing negative-pressure verification and explicit structural-integrity method traceability.
- Tighter connector dimensional, retention, and risk-based functional verification requirements.
- New or expanded performance obligations for haemodialysers, haemodiafilters, haemofilters, and haemoconcentrators, including ultrafiltration rate and endotoxin transfer.
- Updated test-method governance through risk-based sample sizing and final-production/sterilized configuration requirements.
- Expiry-date substantiation using accelerated studies confirmed by real-time aging data.

This document converts the attached ISO 8637-1:2024 versus 2017 comparison into a DHF impact-and-actions recommendation in the same implementation style as the attached DHF reference document.

2. Key Changes Summary

2.1 Biological safety, sterility, and non-pyrogenicity claim traceability

Change: Biological safety and haemocompatibility requirements remain substantively unchanged, but the 2024 edition clarifies pathway scope and strengthens linkage between sterility and non-pyrogenicity compliance and the manufacturer's statements in labelling. It also makes sterilization-record verification explicitly align to ISO 11737-2 and adds a note referencing ANSI/AAMI ST72 in the non-pyrogenicity verification context.

DHF Impact:

- DHF traceability should link SAL, non-pyrogenicity, and biological safety evidence directly to product labelling statements and technical file claims.
- Sterilization validation records should explicitly cite ISO 11737-2, and non-pyrogenicity rationale should document consideration of ANSI/AAMI ST72 where relevant.
- Reusable-device evaluations should continue to show post-reprocessing evidence, but no major new biological test parameters are introduced.

Recommended Actions:

Action	Timeline	Owner	Priority
Update DHF traceability matrix to link sterility and non-pyrogenicity evidence to 7.2 labelling claims	3 weeks	Regulatory / Quality	High
Confirm sterilization validation files explicitly reference ISO 11737-2	3 weeks	Sterilization / Quality	High
Add documented ST72 consideration to non-pyrogenicity rationale where applicable	4 weeks	Biological Safety / Regulatory	Medium
Review reusable-device post-reprocessing biological evidence for continued alignment	4 weeks	Quality / R&D	Medium

2.2 External casing structural integrity and pressure limits

Change: The 2024 edition keeps the 1.5 times maximum positive-pressure requirement, but tightens the negative-pressure expectation for external casing integrity from 700 mmHg (93.3 kPa) to 500 mmHg (66.7 kPa) and explicitly maps verification to specific test methods and hold times. This is primarily a verification and traceability change rather than a more severe load case, but it requires controlled documentation updates.

DHF Impact:

- Design verification protocols and reports must be updated to reference the exact 2024 negative-pressure value and corresponding test methods.
- Legacy reports based on the 2017 method may still be technically conservative, but DHF justification should explain alignment or need for partial reissue/retesting.
- Risk files and specifications should avoid carrying forward obsolete 700 mmHg references where the current standard now cites 500 mmHg.

Recommended Actions:

Action	Timeline	Owner	Priority
Update structural integrity protocols/specifications to 66.7 kPa (500 mmHg) negative-pressure criterion	3 weeks	Test Engineering	High
Review legacy verification reports for reference mismatch and decide on protocol addendum versus targeted retest	4 weeks	Quality / Test Engineering	High
Revise design specifications and risk documentation to remove obsolete 700 mmHg references	4 weeks	Design Engineering / Risk Manager	Medium

2.3 Connector dimensional control and mechanical retention

Change: ISO 8637-1:2024 significantly tightens connector requirements by introducing tables with precise dimensional criteria, more explicit verification methods, dated ISO 80369-7:2021 references, expanded use of validated measurement methods, and stronger retention expectations such as 25 N for 15 seconds for certain non-locking haemoconcentrator connections. Dialysis fluid, filtrate, blood, and haemoconcentrator connector verification is now much more prescriptive and tied to risk-based functional testing.

DHF Impact:

- Drawings, component specifications, gauges, and supplier records must be updated for the current dimensional criteria and connector references.
- Verification plans need validated measurement methods, potentially including analogue gauges, optical systems, 3D X-ray methods, or destructive assessments where necessary.
- Risk management must explicitly define functional compliance and misconnection/retention acceptance criteria for connectors.

Recommended Actions:

Action	Timeline	Owner	Priority
Update connector drawings/specifications to current Figure/Table dimensional criteria and ISO 80369-7:2021 references	4 weeks	Design Engineering	Critical
Obtain or validate connector measurement methods, gauges, and work instructions	6 weeks	Metrology / Test Engineering	Critical
Requalify suppliers or incoming inspection criteria for connector-critical dimensions	6 weeks	Supplier Quality / Procurement	High
Add connector functional compliance criteria to ISO 14971 risk files and verification plans	6 weeks	Quality/Risk / Test Engineering	High
Revalidate haemoconcentrator non-locking retention requirements to 25 N / 15 s where applicable	8 weeks	Test Engineering	High

2.4 New and expanded performance characteristics

Change: The 2024 edition adds new explicit performance requirements for ultrafiltration rate for devices intended for convective therapies and endotoxin transfer for haemodialysers and haemodiafilters. It also expands sieving coefficient expectations to include haemodialysers and allows optional reporting of additional middle molecules when sieving coefficient is at least 0.1.

DHF Impact:

- Devices intended for convective therapies now require DHF evidence for ultrafiltration rate, not only ultrafiltration coefficient.
- Haemodialysers and haemodiafilters need endotoxin-transfer risk evaluation and supporting test evidence linked to pyrogenic response risk.
- Product-family performance matrices, claims tables, and verification protocols must be reviewed to ensure the right device categories receive the expanded testing scope.

Recommended Actions:

Action	Timeline	Owner	Priority
Identify product families affected by new ultrafiltration-rate requirement	2 weeks	Design Engineering / Regulatory	Critical
Develop or update ultrafiltration-rate protocol for convective-therapy products	6 weeks	Test Engineering	Critical
Establish endotoxin-transfer evaluation strategy for haemodialysers and haemodiafilters	6 weeks	Biological Safety / Test Engineering	Critical