APRIL 11, 2026

ISO 8637-3_2024 VERSUS ISO 8637-3_2018 EXTRACORPOREAL SYSTEMS FOR BLOOD PURIFICATION

STANC KONE LLP
Revision;01

ISO 8637-3_2024 VERSUS ISO 8637-3_2018 RIVISION: 01

Report Description	ISO 8637-3_2024 VERSUS ISO 8637-3_2018
Industry Type	HEALTHCARE
Document Type	PRE-AUDITED
Summary of changes	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.

Disclaimer:

This document has been prepared as an independent gap assessment and impact analysis based on a review of applicable standard requirements and generally accepted industry practices at the time of preparation. Referenced ISO standards remain copyrighted property of ISO.

This assessment is intended solely for internal quality planning, risk evaluation, and audit readiness purposes. It does not constitute certification, audit, regulatory approval, or a declaration of compliance with any ISO or other industrial standard.

Responsibility for implementation of recommended actions and for achieving and maintaining compliance with applicable standards and regulatory requirements remains with the organization.

No representation or warranty is made that implementation of the recommendations herein will guarantee certification, regulatory approval, or audit outcome.

1.0 Comparison Table:

Below Table describes the alignment clause-by-clause between the two versions of the ISO standard, which can be fully aligned (**Full**) or partially aligned (**Part**) or not aligned (**Not**) or not applicable (**NA**)

Clause ISO 8637-3 2024	Requirement ISO 8637-3 2024	Clause ISO 8637-3 2018	Requirement ISO 8637-3 2018	Alignment	Remarks
4 Requirements	In essence, plasmafilters must be designed with patient safety at the forefront. Any part that touches blood needs to be proven free from biological risks, with attention to local and international standards for biocompatibility. The blood and filtrate pathways aren't just expected to be sterile—they also must not introduce pyrogens, since both contamination and fever-inducing substances could compromise patient health. This highlights the dual focus: strict scientific validation and compliance with regulatory expectations.	**4 Requirements 4.1 B iological safety**	The focus here is on ensuring that any part of the device that comes into contact with blood—whether directly or indirectly—has been proven safe for its intended clinical use. That means biocompatibility testing is essential to rule out biological hazards. Manufacturers also need to be mindful of national regulations and standards on toxicology and biocompatibility, both where the device is made and where it will be marketed. Ultimately, compliance isn't just about internal validation; it must be formally verified to demonstrate that the device meets both scientific and regulatory expectations.	Part	2024 splits 2018's combined biological safety/biocompatibility (4.1) into three clauses—biological evaluation (4.1), sterility (4.2), and non-pyrogenicity (4.3)—removing explicit biocompatibility wording.

4.4.1 Structural integrity	This point is really about the strength and reliability of the plasmafilter's casing. It has to withstand pressures well beyond normal use—both higher than the maximum operating pressure and significantly below atmospheric pressure. In short, the casing is tested to prove it won't crack or fail under stress, ensuring patient safety and dependable performance.	**5 .5 Mechanical characteristics** **5 .5 .1 Structural integrity**	This section is really about proving the toughness of the device's casing. It must hold up against pressures far above normal use—both strong positive pressure and deep negative pressure, even at high elevations. The test involves filling the device with water, keeping it under elevated pressure for ten minutes, and checking for leaks. In short, it's a stress check to ensure the casing stays intact and reliable under extreme conditions.	Part	2024 tightens negative pressure limit to 66.7 kPa (500 mmHg) from 2018's 93.3 kPa (700 mmHg), refines test methods (degassed water at 37°C, detailed procedures in 5.5.1.2/5.5.1.3 vs. simpler water fill), and shifts clause numbering.
4.4.2 Blood compartment integrity	This section is really about proving the blood compartment can handle extreme stress without failing. When tested at 1.5 times the maximum recommended transmembrane pressure, it must show no leakage. In short, it's a safeguard to confirm the compartment's integrity and ensure patient safety under demanding conditions.	**5 .5 .2 Blood compartment integrity**	This section is essentially about testing the blood compartment's integrity under pressure. The filter is set upright, sealed, filled, and pressurized to 1.5 times the maximum transmembrane level. If no bubbles appear in the filtrate port, it confirms the compartment is sound. In short, it's a straightforward leak check to ensure the device can safely withstand stress.	Part	2024 version replaces 2018's prescriptive air-pressure test (vertical setup, 10 min, no bubbles via filtrate port) with a performance requirement—no blood compartment leak at 1.5x max TMP—verified by manufacturer-validated records review.