APRIL 7, 2026

ISO 8637-1:2024 VERSUS ISO 8637-1:2017

EXTRACORPOREAL SYSTEMS FOR BLOOD PURIFICATION PART 1: HAEMODIALYSERS, HAEMODIAFILTERS, HAEMOFILTERS AND HAEMOCONCENTRATORS

STANCE KONE LLP
Revision;01

ISO 8637-1:2024 VERSUS ISO 8637-1:2017

Report Description	Gap assessment showing ISO 8637-1:2024 versus ISO 8637-1:2017.
Industry Type	Medical device
Document Type	Pre-audit record
Summary of changes	ISO 8637-1:2024 remains largely aligned with ISO 8637-1:2017, with many clauses unchanged or only editorially clarified, so most existing designs and core performance characteristics remain acceptable in principle. The main gaps arise from tighter mechanical/connector requirements and stronger traceability between labelling, test evidence, and risk management.

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**).

Clause ISO 8637-1-2024	Requirement ISO 8637-1-2024	Clause ISO 8637-1-2017	Requirement ISO 8637-1-2017	Alignment	Remarks
4 Requirements **4.1 Biological safety and haemocompatibility**	Parts of the device that come into direct or indirect contact with blood are assessed for biological safety in line with toxicology and biocompatibility principles. For devices labeled as reusable, testing is carried out after reprocessing according to the manufacturer's instructions. Consideration is also given to whether national regulations or standards on toxicology and biocompatibility apply in the country of manufacture and in the countries where the device will be marketed.	**4 Requirements** **4.1 Biological safety**	Device components that come into direct or indirect contact with blood are examined for biological safety, with reference to toxicology and biocompatibility considerations. For reusable devices, testing is performed after reprocessing in line with the manufacturer's instructions. Evaluation also takes into account whether national regulations or standards on toxicology and biocompatibility are in place in the country of manufacture and in the countries where the device will be marketed.	Full	No substantive changes between 2024 and 2017 versions. Both require biological safety evaluation per 5.2 for blood-contacting parts, post-reprocessing testing for reusables, and national toxicology/biocompatibility checks.

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4.2 Sterility	The blood and fluid pathways of the circuit, along with the internal mating surfaces of connectors that come into direct or indirect contact with blood during use, are expected to be sterile. Verification of sterility is aligned with the referenced conformity assessment. Elements of the circuit that do not have any direct or indirect contact with blood are not subject to sterility requirements.	**4.2 Sterility**	The blood pathway of the device is expected to be sterile, with conformity verified through the referenced sterility assessment procedure.	Part	2024 adds explicit compliance with manufacturer's sterility statement (7.2 h labeling); 2017 lacks this. DHF impact: document SAL, process validation linkage to labeling claims—no parameter changes.
4.3 Non-pyrogenicity	The blood pathway of the device is characterized as non-pyrogenic, consistent with the manufacturer's stated specification. Verification of this non-pyrogenic state is carried out in accordance with the referenced conformity assessment procedure.	**4.3 Non-pyrogenicity**	The blood pathway of the device is described as non-pyrogenic, with conformity verified through the referenced assessment procedure.	Part	2024 adds compliance with manufacturer's non-pyrogenicity statement (7.2 h labeling); 2017 lacks this. DHF impact: document testing records, linkage to labeling claims—no parameter changes

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