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ISO 7199:2017 VERSUS ISO7199:2024 THIS DOCUMENT SPECIFIES REQUIREMENTS FOR STERILE, SINGLE-USE, EXTRACORPOREAL BLOOD-GAS EXCHANGERS STERILE, SINGLE-USE, EXTRACORPOREAL BLOOD-GAS EXCHANGERS

STANC KONE LLP
Revision; 01

ISO 7199:2017 VERSUS ISO 7199:2024
RIVISION:01

Report Description	Gap assessment showing ISO 7199:2024 VERSUS ISO 7199:2017
Industry Type	Healthcare
Document Type	Pre-audited
Summary of changes	Based on the clause-by-clause comparison between ISO 7199:2024 and ISO 7199:2017, the 2024 edition introduces several substantive changes affecting biological safety, physical integrity testing, connector standards, performance validation, and documentation practices..

ISO 7199:2017 VERSUS ISO 7199:2024
RIVISION:01

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 7199-2024	Requirement ISO 7199-2024	Clause ISO 7199-2017	Requirement ISO 7199-2017	Alignment	Remarks
4 Requirements **4.1 Biological characteristics** **4.1.1 Sterility and non-pyrogenicity**	The 2024 framework emphasizes that the blood pathway must be validated for sterility and absence of pyrogenic substances. Verification is tied to a defined test method, underscoring the expectation that manufacturers demonstrate conformity through standardized evaluation rather than relying solely on design intent.	**4 Requirements** **4.1 Biological characteristics** **4.1.1 Sterility and non-pyrogenicity**	The 2017 framework places emphasis on ensuring the blood pathway is both sterile and free from pyrogenic contamination. Conformity is expected to be demonstrated through a prescribed verification method, reflecting the regulatory intent to anchor safety assurance in standardized testing rather than manufacturer declarations.	Full	No textual gaps exist between ISO 7199:2017 and 2024 for clause 4.1.1 (sterility/non-pyrogenicity of blood pathway) and 5.2.1 (verification via referenced standards).

4.1.2 Biocompatibility	The standard emphasizes that every component in contact with blood must be evaluated for biocompatibility in relation to its intended clinical role. This reflects the broader regulatory expectation that patient safety hinges on material compatibility, and verification is tied to established test protocols rather than manufacturer discretion.	**4.1.2 Biocompatibility**	The 2017 standard underscores the expectation that all blood-contacting components undergo biocompatibility evaluation aligned with their intended clinical role. This reflects the regulatory focus on patient safety through material compatibility, with conformity tied to a defined verification protocol rather than discretionary assessment.	Full	No textual gap in clause 4.1.2; 5.2.2 gap removes "ISO 10993-7" reference in 2024.
4.2 Physical characteristics **4.2.1 Blood pathway integrity**	The 2024 standard highlights the importance of verifying blood pathway integrity under defined test conditions, reflecting regulatory emphasis on patient safety through leak prevention. The reference to a specific test method signals that compliance is not left to subjective judgment but must be demonstrated through standardized evaluation, reinforcing consistency across device assessments.	**4.2 Physical characteristics** **4.2.1 Blood pathway integrity**	The 2017 standard places emphasis on demonstrating blood pathway integrity through a defined test method, underscoring the regulatory priority of preventing leakage as a critical safety safeguard. By linking conformity to a prescribed evaluation procedure, the clause reflects the broader intent to ensure uniformity and reliability in how device performance is validated across manufacturers.	Full	No gaps in core blood pathway leak requirement (4.2.1/5.3.1) or parameters between ISO 7199:2017 and :2024. Sole addition in 2024: pulsatile-mode worst-case dynamic testing for applicable blood gas exchangers, potentially needing new DHF data. No cross-clause impacts.