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ISO 1135-5:2015 versus ISO 1135-5:2025

Transfusion equipment for medical use

Part 5: Transfusion sets for single use with pressure infusion apparatus.

STANC KONE LLP
RIVISION:01

ISO 1135-5 2025 Versus ISO 1135-5 2015

Revision:01

Report Description	Gap assessment showing ISO 1135-5:2025 VERSUS ISO 1135-5:2015
Industry Type	Healthcare
Document Type	Pre-audit record
Summary of changes	Based on the clause-by-clause comparison between ISO 1135-5:2025 and ISO 1135-5:2015, the 2025 edition introduces several substantive changes affecting design verification, performance validation, sterility safeguards, connector standards, and risk documentation.

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 EVS EN ISO 1135-5 2025	Requirement EVS EN ISO 1135-5 2025	Clause EVS EN ISO 1135-5 2015	Requirement EVS EN ISO 1135-5 2015	Alignment	Remarks
4 General requirements **4.1**	The 2025 edition standardizes terminology for transfusion set components, with Figure 2 serving as the reference point for consistent nomenclature across designs and documentation.	**4 General requirements** **4.1**	The 2015 edition also anchors transfusion set terminology to Figure 2, ensuring consistency in how component names are applied across technical references and compliance documentation.	Full	No gaps in the nomenclature clause for transfusion set components between 2015 and 2025 version.

4.2 Maintenance of sterility	In the 2025 edition, transfusion sets are expected to include protective caps, reflecting the emphasis on maintaining sterility and safeguarding connection points during storage and handling.	**4.2 Maintenance of sterility**	The 2015 edition highlights protective caps as a sterility safeguard, intended to shield the internal parts of the transfusion set until use, underscoring the focus on contamination prevention during storage and handling.	Full	2025 clause omits 2015's explicit sterility maintenance purpose for protective caps; anyway, adds details in 6.13/9.2g on contamination/stick injury prevention and labelling.
5 Materials	The 2025 edition ties material conformity for transfusion sets to baseline requirements in Clause 6, while adding stricter provisions for any components that contact blood or blood products, requiring alignment with Clauses 7 and 8 to address biocompatibility and safety considerations.	**5 Materials**	The 2015 edition links transfusion set materials to baseline conformity requirements in Clause 6, while adding specific provisions for blood-contacting components. These must also meet the stricter criteria in Clauses 7 and 8, reflecting the regulatory focus on biocompatibility and patient safety.	Full	No technical gap identified; the change is purely editorial.