KEIT · Instrument Sterilization and Traceability …

KEIT DAY HOSPITAL

Instrument Sterilization and Traceability Protocol

Official Manual of Clinical, Care and Organizational Protocols

Document Code	KEIT-SOP-08	**Version**	2.0
Revision	02	**Status**	Official
Issue Date	28/03/2026	**Next Review**	28/03/2027
Prepared by	Medical Directorate / Quality	**Approved by**	_____
Signature and Date	_____	**Distribution**	Controlled - Internal Use

Purpose of the document. To officially define the scope, responsibilities, operating procedure, KEIT standards, records and protocol review criteria.

1. Document Control Information

Application	All clinical, nursing, technical and organizational personnel involved in the described process.
Archiving	KEIT internal document management system and controlled copy in the relevant areas.
Review	At least annually or earlier in the event of regulatory, organizational or technological updates.

1.Scope of Application

This protocol applies to surgical instruments, reusable instruments, procedural sets and devices requiring sterilization.

2. Responsibilities

- **Sterilization unit personnel or dedicated area personnel:** performance of sterilization cycles in accordance with the protocol.
- **Scrub nurse and Operating Room Coordinator:** verification of the availability of sterile sets before surgery.
- **Medical Directorate:** verification of compliance with the traceability system.

3. Operating Procedure

- Receive contaminated material in the dedicated area and immediately begin decontamination and cleaning according to the established procedure.
- Dry the instruments, inspect their integrity and assemble the sets in a standardized manner.
- Package the instruments using materials suitable for sterilization and storage.
- Perform the cycle in a validated and monitored autoclave, recording the required physical, chemical and biological parameters.
- Release sterile material only after verifying that the cycle result is compliant.
- Store sterile sets in a clean and protected area, ensuring proper rotation and full traceability.
- Treat as non-conforming any set for which there is uncertainty regarding integrity, date, packaging or processing.

4. KEIT Operational Standards

- KEIT uses autoclaves with cycle recording and documented traceability.
- Surgical sets are prepared and stored according to a clearly defined contaminated-to-clean workflow.
- Any non-conformities are documented and discussed during internal audits.

5. Records and Documentation

- Autoclave cycle register.
- Chemical and biological indicators.
- Traceability records for sterile sets.
- Non-conformity register.

6. Review and Updates

Periodic review including verification of autoclave qualification and process audits.

Implementation Note

This document is an internal operational draft. Before final adoption, review by the Medical Directorate, Clinical Directorate, Legal Advisor and the relevant department managers is recommended.

6. Related Attachments and Forms

- Operational checklists, recording forms, audit sheets and maintenance registers applicable to this protocol.
- Any department-specific or equipment-specific technical attachments are referenced in the relevant local operating instructions.

7. Final Approval

Position	Name and Signature	Data
Medical Directorate	_____ _____	_____