



Sterilization Monitoring Guide

A complete guide to chemical and biological indicators — types, placement, reading and documentation.

Why monitor sterilization?

A sterilizer that completes its cycle has not necessarily sterilized its load. Air pockets, wet steam, overloading and incorrect packaging can leave instruments non-sterile while the display reads "complete". Monitoring provides independent evidence, for each cycle and each pack, that sterilizing conditions were achieved.

The three monitoring methods

Physical: the sterilizer printout of time, temperature and pressure — check and sign for every cycle.

Chemical: ISO 11140-1 indicators that change colour when exposed to critical variables — immediate, pack-by-pack information.

Biological: resistant spores that prove lethality — the reference test, needing incubation.

Chemical indicator types (ISO 11140-1)

Type	Name	Use
1	Process indicator	Outside every pack (tape, pouch print)
2	Specific test	Bowie-Dick air-removal test
3	Single-variable	Rarely used
4	Multi-variable	Inside packs
5	Integrating	Inside packs, load release
6	Emulating	Cycle-specific verification

Where to place indicators

- Type 1 tape across the closure of every wrapped pack; pouches carry a printed Type 1 indicator.
- Type 4/5/6 strip inside each pack, in the location hardest for the sterilant to reach (centre of linen packs, bottom of dense trays).
- Bowie-Dick pack alone in the chamber, lowest shelf above the drain, every day after warm-up.
- Biological indicator in a process challenge device at least weekly and with every implant load.

Reading and recording results

- Compare the indicator with the printed reference colour; any incomplete or streaky change means reprocess.
- Record sterilizer number, cycle, load, operator, physical parameters and indicator results for every cycle.
- Retain records for the period required by your regulator so any pack can be traced to its cycle.

Kangde Med monitoring products

- Steam, EO and plasma indicator tapes (Type 1)
- Class 4, Class 5 and Class 6 steam indicator strips
- EO, plasma and formaldehyde indicator strips (Type 4)
- Custom Class 6 designs for 90-140 °C cycles



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