

Corrigendum

Revised Specification

**Specification Of ETO Biological Indicator**

- Should be ETO sterilized
- Should have thermoplastic vial and cap
- Should have crushable media ampoule which contains modified Trypticase™ Soy Broth (TSB) with a pH indicator
- Should have a shelf life of 2-3 years
- It should be compatible with PurETO's ETO Sterilizing machine
- Should have modified TSB will transition colour and/or demonstrate turbidity in the presence of bacterial growth
- Should have inoculated carrier (disc) of Bacillus atrophaeus with a population level of  $10^6$
- Should give result in 2-4 hours
- Should be NS-EN ISO 13485 (latest) and ISO 11138-1(latest), BIS, CDSO, EUCF, four-digit body certified.
- Every box should contain Quality Assurance certificate with mention of Spore population, D- value & Z value.

Specification	Specification Name	Bid Requirement	Representation by 3M as per mail	Remarks by CSSD Department
Generic	Material	Plastic, Propylene, Glass	Ok	Ok
Technical specification	Readout Technology	Fluorescence detection, pH colour change, turbidity	Ok	Ok
	Spore Population	Equal more than $10^5$ cfu/strip, more than 100000 cfu/strip, less than 100000 cfu/strip	Compliant with ANSI/AAMI/ISO11138:2006 and USFDA approved	Amended in Specification
	Time taken for BI result	Equal or less than 15 min, 16 min, to 24 min – 25 min, 3 hour, 3-48 hours, greater than 48 hours	24 min to 240 min, result shown in all dept online.	Accepted
	Sterilization process	Steam, H2O2 plasma, EO Gas, Gamma, E-beam	EO Gas	Accepted
Self-life	Self-life period	9-36 months	24 months or above	Accepted

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### Specification of Steam Biological Indicator

- Is can be used for organism test
- Should be steam sterilized
- Should provide result within 20-30 minutes
- Should be available in self-contained vials
- Organism pollution rate should be  $10^5$  or more
- The organism group should have Geobacillious Stearothermophilus with proper indication of lot no. expiry date
- Should be NS-EN ISO 13485 (latest) and ISO 11138-1(latest), BIS, CDSCO, EUCF, four-digit body certified
- Should have a shelf life of 18 months or more

Specification	Specification Name	Bid Requirement	Representation by 3M as per mail	Remarks by CSSD Department
Self-life	Self-life period	3 years	24 months or above	Amended in Specification

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