

[organization name]

### Appendix 1 – Record for Sterilization

Date:			
Sterilization method:			
Exposure			
Gas concentration			
Time:			
Temperature:			
Operator:			
Chemical Indicator/Integrator			
Pass:		Fail:	
Sterilization Validation Report			
Test name:			
Product name:		Batch number:	
Date:		Test conducted by:	[name], [job title]

**Commented [AES1]:** This appendix is just an example, the [redacted]

**Commented [AES2]:** E.g., Relative humidity ~35 – 80%

**Commented [AES3]:** Delete this row if the organization does [redacted]

**Commented [AES4]:** E.g., Gas quantity >400mg/L

**Commented [AES5]:** E.g., Exposure time ~90 – 360 minutes

**Commented [AES6]:** Delete this row if organization does not [redacted]

**Commented [AES7]:** E.g., Temperature ~45°C

**Commented [AES8]:** Delete this row if the organization does [redacted]

**Commented [AES9]:** E.g., 1, 8, 12, 17, and 24 hours

**Commented [AES10]:** Delete this row if the organization does [redacted]

**Commented [AES11]:** E.g., 50 kGy

**Commented [AES12]:** E.g., nominal porosity of 0.2 µm or 0.22 µm

**Commented [AES13]:** Delete this row if organization does not [redacted]

**Commented [AES14]:** Add additional rows if multiple tests are conducted.

**Commented [AES15]:** E.g., bioburden validation

**Commented [AES16]:** E.g., 34

**Commented [AES17]:** E.g., <40

[job title]

[name]

[signature]

**Commented [AES18]:** Only necessary if the Procedure for Document and Record Control prescribes that paper documents must be signed.