

# Validation Template

## 1. Performance Qualification

HEAT DISTRIBUTION STUDIES (attach results as evidence if previously done)

The cold spot is located .....

## 2. Operational qualification

### Physical Qualification

HEAT PENETRATION STUDIES

The densest / challenge load is recorded below and positions are referenced. I.e. Position 1 may be next to hinge. Indicate which pack is to be tested.

**Table 1**

Rack Position	Pouch Contents
1.	
2.	
3.	
4.	
5.	
6.	
7.	

Or  
Attach the layout in a diagram.

### For the service agent to provide results (attach) and for you to complete

- A Penetration Time = (underline this on attached evidence if it is measurable) .....
- B Attach evidence that the time at temperature test has been done and whether any adjustments to the time settings are required by the user. ....
- C Drying time of .....minutes is recommended by the manufacturer. Is this adequate / inadequate? If inadequate it was altered to
- D Indicate if you wish to combine this test with your first BI test cycle  Yes  No

Signature: .....

### For staff to complete from service technician's results

- A Holding Time recommended by manufacturer = ..... Mins
- B Results of penetration time = ..... Secs / mins
- C 3 minutes at 134°C is required then add penetration time = ..... Mins
- D The result for °C must be equal or less than A or an adjustment is required.

Signature: .....

# Validation Template

**For staff to complete**

- A Date of annual validation \_\_\_\_\_
- B Identification of Steriliser being validated \_\_\_\_\_
- C Date of Service \_\_\_\_\_
- D BI batch number \_\_\_\_\_
- E The temperature, time and pressure for validation \_\_\_\_\_

**Microbiological Qualification**

Preparing and using tests

Label 7 BIs as shown below with a marker pen. C is the unprocessed control. Place one each in denset pack in cold spot and over drain and run cycle. Allow to cool before crushing inner glass tube if incubating tests on site. Otherwise send intact for incubation of all 7 for 48 hrs at 56 degrees.

Note: If the Bis turn brown after sterilisation, refer to section 3 on validation

**Table 2**

BI Number	Cycle Number	Position	BI 48 hour Result
1A.	1	Over Drain	
1B.	1	Challenge Pack	
2A.	2	Over Drain	
2B.	2	Challenge Pack	
3A.	3	Over Drain	
3B.	3	Challenge Pack	
C.	Unprocessed	-	

All processed results must be purple and the control yellow for a pass result.

Printer / indicator for each cycle showed PASS. Sign \_\_\_\_\_

BI Remained purple so that its' result for each cycle showed PASS. The control changed to yellow also indicating PASS.

Name \_\_\_\_\_ Sign \_\_\_\_\_

Responsible person to sign off on Validation of sterilisation process

Name \_\_\_\_\_ Sign \_\_\_\_\_

Date \_\_\_\_\_