

## Performance Qualification Record

Process for Performance Qualification:

- a. Fill container or tray(s) with medical devices, it would hold in use, to create Tray Set.
- b. All test sets are exposed to the same sterilization process in 3 separate full load cycles to demonstrate reproductivity.
- c. Place a Biological and Chemical Integrator in every corner and in the centre of every layer.
- d. Every test set encompasses variations such as time of day tested, operator, and package content (always include worst case scenario packages).
- e. Tests are processed – decontaminated, prepared and repackaged – between tests.
- f. Performance qualification is done very time there are changes in sets or trays.

**Test #1**

Date: \_\_\_\_\_ Time: \_\_\_\_\_ Staff ID: \_\_\_\_\_

Family(s) Tested: \_\_\_\_\_

Description of Sets or Trays: \_\_\_\_\_

Closure used: \_\_\_\_\_ Label used: \_\_\_\_\_

Steam Sterilizer #: \_\_\_\_\_ Temp: \_\_\_\_\_ Exposure Time: \_\_\_\_\_ Drying Time: \_\_\_\_\_

Load Sticker – attach below

Integrator Sticker – attach below

### Results

Number of Chemical Integrators placed in Container or Tray(s): \_\_\_\_\_ Pass Fail

Number of Biological Indicators placed in Container or Tray(s): \_\_\_\_\_ Pass Fail

Copy of Sterilizer Printout Yes No

Moisture in Tray or Container Yes No

FINAL Results: Pass Fail

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

## Performance Qualification Record

**Test #2**

Date: \_\_\_\_\_ Time: \_\_\_\_\_ Staff ID: \_\_\_\_\_

Family(s) Tested: \_\_\_\_\_

Description of Sets or Trays: \_\_\_\_\_

Closure used: \_\_\_\_\_ Label used: \_\_\_\_\_

Steam Sterilizer #: \_\_\_\_\_ Temp: \_\_\_\_\_ Exposure Time: \_\_\_\_\_ Drying Time: \_\_\_\_\_

Load Sticker – attach below

Integrator Sticker – attach below

### Results

Number of Chemical Integrators placed in Container or Tray(s): \_\_\_\_\_ Pass Fail

Number of Biological Indicators placed in Container or Tray(s): \_\_\_\_\_ Pass Fail

Copy of Sterilizer Printout                      Yes                      No

Moisture in Tray or Container                      Yes                      No

FINAL Results:                      Pass                      Fail

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

## Performance Qualification Record

**Test #3**

Date: \_\_\_\_\_ Time: \_\_\_\_\_ Staff ID: \_\_\_\_\_

Family(s) Tested: \_\_\_\_\_

Description of Sets or Trays: \_\_\_\_\_

Closure used: \_\_\_\_\_ Label used: \_\_\_\_\_

Steam Sterilizer #: \_\_\_\_\_ Temp: \_\_\_\_\_ Exposure Time: \_\_\_\_\_ Drying Time: \_\_\_\_\_

Load Sticker – attach below

Integrator Sticker – attach below

### Results

Number of Chemical Integrators placed in Container or Tray(s): \_\_\_\_\_ Pass Fail

Number of Biological Indicators placed in Container or Tray(s): \_\_\_\_\_ Pass Fail

Copy of Sterilizer Printout                      Yes                      No

Moisture in Tray or Container                      Yes                      No

FINAL Results:                      Pass                      Fail

Signature: \_\_\_\_\_ Date: \_\_\_\_\_