

**Protocol annual re-qualification (OQ - PQ).**

**OQ sterilizers SS1 and SS2. The following tests are to be included:**

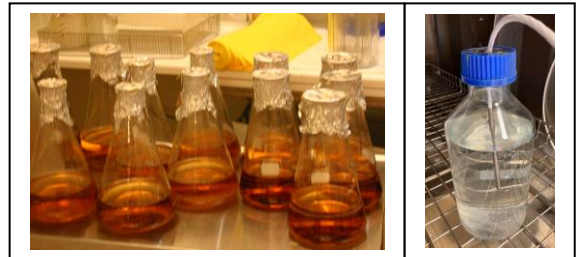
- Air leakage test, before and after the connection of the test equipment. Total 3 tests.
- Automatic control test
  - Automatic control test
  - Thermometric test
  - Verification of instrument calibration.
- Bowie & Dick test 134° C (only SS1).
- Air detector Function test (only SS1).
- Hollow load test (only SS1).

**PQ - Reference loads SS1 and SS2 programs.**

**1. Liquid program: 121 ° C for 20 minutes with a short pre-vacuum (open liquid)**

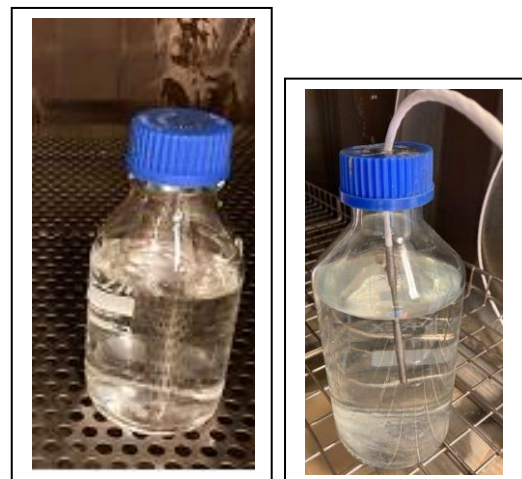
**Max. load.**

Thermometric verification of glass flasks 2 liters with 1 liter of growth broth 12 flakes + reference probe in defined volume of water.



**Min. load.**

Thermometric verification of glass bottle 500 ml distilled water + reference probe in defined volume of water.



## 2. Sterilization filter housing 121 degrees 20 min - extended dry

### Max load:

Thermometric verification of filter housing with filter foil package 15 pcs

### Min. load:

Thermometric verification of filter housing with filter foil package 2 pcs



## 3. Standard program 121 ° C for 20 min for mixed load. (equipment load, film / paper bags, grates wrapped in sterilizing paper)

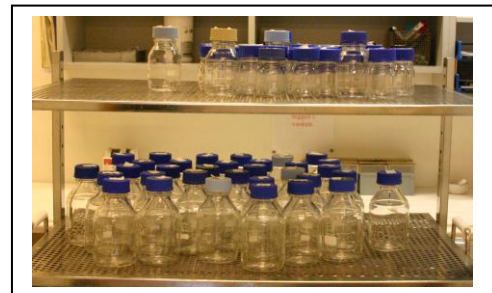
**Max load:** The type and amount of equipment is limited. Composition will be by agreement between the purchaser and the supplier.

**Min. load:** The type and amount of equipment is limited. Composition will be by agreement between the purchaser and the supplier.

## 4. Standard program 134 ° C for 5 min for mixed load. (equipment load, film / paper bags, grates wrapped in sterilizing paper)

### Max. load:

Thermometric verification of various glass sizes with cap 40 - 50 pcs



### Min.load:

Thermometric verification of mixed load of various glass, plastic, tweezers and scissors wrapped in film / paper bags.



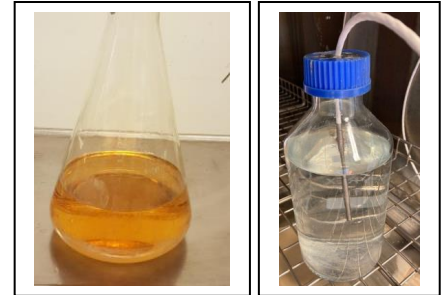
**OQ-PQ - Reference loads LWS programs.**

**1. Air leakage test, before and after the connection of the test equipment**

**2. Make safe contained liquid discard load 134°C**

**Max. load:**

Thermometric verification of liquid in 5 liters glass flask with 2 liters of growth broth + reference probe in defined volume of water.



**3. Make safe small plastic discard load 134°C**

**Max. load:**

Thermometric verification of mixed load contained of plastic and glass reagents with and without liquid, with and without cap in open autoclavable waste bag (hazard bag) placed in open steel container + reference probe in defined volume of water from installation validation. Minimum use of two thermocouples in the load, one in center, and one in bottom of load.

