

1. AIM:

Aim of this procedure is to define a routine monitoring test for the tightness of lid and gasket.

2. SCOPE AND RESPONSIBILITIES

The Scope of this document includes the preparation of an area for testing and the verification of the process i.e. water check.

The test procedure should be performed by educated personnel.

3. REFERENCES AND RELATED DOCUMENTS:

ISO 9001

ISO:13485

4. DEFINITIONS AND ABBREVIATIONS:

Verification Process – This is a water leak check, using distilled or demineralized water.

5. VERIFICATION PROCESS (WATER CHECK):

1. Establish sufficient uncluttered working area.
2. Open the container and empty out the complete content (e. g. trays, instruments etc.).
3. Pour 0,5 – 0,8 liters distilled/de-ionized water into the container.
4. Place lid on the prepared container base.
 - a. Center the lid and latch the sides.
5. Grab the handles to the left and right of the base.
6. Lift the container straight up horizontally, then rotate the container for approximately 90° towards you.
 - a. This will allow the water to travel along the sealing area and cover the whole gasket.
7. Slowly rotate the base to the left and right to assure that water has covered the entire inner perimeter of the closed container
 - a. This will assure that sufficient water also covers the corners and latch areas along the short and long sides.

8. Look for any sign of water leaking through the assembled container (lid and body) during the left/right rotation process.

9. If no leaks are identified proceed with step 13.

10. If water is leaking at a rate of more than (2) drops per minute:

- a. Remove the lid by dis-engaging the side latches.
- b. Check lid and base:
 - b.1 A gasket check should be performed > there should be no deformation or tear in the gasket.
 - b.2 Check if hinges and lid close well.
- c. Assure that no non-conformance is identified.
- d. Wipe (lint free) any excess water from gasket area around the perimeter of the lid.
- e. Repeat steps 3 to 8 as described above.

11. If lid/gasket continues to leak:

- a. Call your service provider for maintenance.

12. If water is still leaking through the lid/gasket after the completion of step 11:

- a. Set component/s aside and follow your facilities specific NCR process.

In case of no leaks:

13. Place the container on the table.

14. Remove the lid by disengaging the side latches.

15. Wipe (lint free) any excess water from gasket area around the interior perimeter of the lid and the interior of the base.

- a. Use properly managed compressed air as an option for water removal.
- b. Make sure you removed any excess water to avoid water spots/stains.