

CLAIMS

1. A sealing arrangement (1) comprising a gasket (5) arranged to seal a gap (2) formed between a first element (3) and a second element (4), wherein the gasket is arranged to be located in the gap (2) and to be in contact with the first and the second elements (3,4),
5 **characterised in that** the gasket comprises two elongated gasket members (6,7) located on a distance from each other so as to form an intermediate gasket space (8) confined by the gasket members (6,7) and said first and second elements (3,4), and in that the sealing arrangement further comprises a pressure source (10) adapted to apply a pressure on the intermediate gasket space (8), said pressure source preferably being configured to maintain a set pressure
10 difference towards the surroundings.
2. The sealing arrangement of claim 1, wherein the pressure source is arranged in fluid communication with the intermediate gasket space (8) between the gasket members (6,7) via a channel or conduit (12; 120, 121).
3. The sealing arrangement of any one of claims 1 or 2, wherein the first element is
15 comprised in a frame (13) of a filter (14) and the second element is comprised in a mounting structure (15) against which the filter is mounted.
4. The sealing arrangement of any one of claims 2 or 3, wherein the channel or conduit (120) is arranged to be connected to the intermediate gasket space (8) through the mounting structure (15).
- 20 5. The sealing arrangement of any one of claims 2 or 3, wherein the channel or conduit (12) is arranged to be connected to the intermediate gasket space (8) through the frame (13) of a filter (14).
6. The sealing arrangement of any one of claims 1-5, wherein the sealing arrangement further comprises an control sensor (16) located between the pressure source and the
25 surroundings, said control sensor (16) preferably being configured to communicate with an evaluation device (17).
7. The sealing arrangement of any one of claims 1-6, further comprising a backup pressure source (18) arranged parallel to the pressure source (10).
8. The sealing arrangement of any one of claims 1-7, wherein the pressure source (10) is
30 an air pump or a pressure tank.

9. The sealing arrangement of any one of the preceding claims, wherein the distance between the two elongated gasket members (6,7) is 0.5 to 100 mm, preferably 2-90 mm, more preferably 5-50 mm.

10. The sealing arrangement of any one of the preceding claims, wherein the height of the gap (2) is the distance between the first element (3) and the second element (4), and is 0.5 to 50 mm, preferably 1-40 mm.

11. The sealing arrangement of any one of the preceding claims, wherein the cross-sectional area of the intermediate gasket space (8) is 0.25 to 5000 mm², preferably 2-2000 mm².

12. The sealing arrangement of any one of claims 1-11, wherein the sealing arrangement further comprises a leakage monitoring device (9) comprising a leakage sensor (11) positioned in the conduit between the pressure source (10) and the intermediate gasket space (8).

13. The sealing arrangement of claim 12, wherein the leakage sensor (11) is an air flow sensor or a pressure sensor.

14. The sealing arrangement of claim 13, wherein the leakage sensor (11) is a thermal airflow sensor, pressure drop measurement device for measurement over capillaries or orifices, rotating vane, vortex meter, or ultrasonic flow meter.

15. The sealing arrangement of any one of claims 12-14, wherein the leakage sensor (11) is configured to communicate with an evaluation device (17).

16. A method (100) comprising applying a pressure (101) to the intermediate gasket space (8) of one or more sealing arrangements as defined in any one of claims 1-15 by means of the pressure source (10).

17. The method of claim 16, comprising continuously applying pressure to the intermediate gasket space (8) by means of the pressure source (10).

18. The method of claim 16 or 17, further comprising monitoring of leak tightness

- obtaining a leakage detection value (102) from a leakage sensor (11),
- comparing said leakage detection value (103) with a setpoint value; and
- if said leakage detection value from the leakage sensor (11) is equal to, or exceeds said setpoint value, generating a message (104) indicating leakage.

19. The method of claim 18, wherein the monitoring of leak tightness is performed continuously, by continuously applying pressure to the intermediate gasket space (8) by means of the pressure source (10), and continuously obtaining the leakage detection values from the leakage sensor (11).

5 20. The method of any one of claims 16-19, further comprising obtaining a control value (105) from a control sensor (16); and, if said control value from the control sensor deviates from a control setpoint value, establishing (106) that the pressure source (10) is not operating.

 21. The method of claim 20, comprising continuously obtaining said control value from the control sensor and continuously comparing said control values with the control setpoint
10 values.

 22. The method of claim 21, further comprising activating (107) the backup pressure source (18) if said control value from the control sensor (16) deviates from said control setpoint value.

 23. The method of any one of claims 16-22, wherein in the pressure is applied by the
15 pressure source (10) to the intermediate gasket space (8) so as to create positive pressure difference relative to the surroundings.

 24. The method of any one of claims 16-22, wherein in the pressure is applied by the pressure source (10) to the intermediate gasket space (8) so as to create a negative pressure difference relative to the surroundings .

20 25. The method of any one of claims 16-24, wherein in pressure is applied by the pressure source such that the pressure difference between the intermediate gasket space and the surrounding is 50 Pa-1000 kPa, preferably 1 kPa-500 kPa.

 26. A system comprising one or more confined volumes (19a,19b), each volume being sealed by a sealing arrangement as defined in any one of claims 1-15, wherein the intermediate
25 gasket space (8a,8b) of each sealing arrangement comprised in the system is preferably connected to the same pressure source (10).

 27. The system of claim 26, further comprising an evaluation device (17); wherein the intermediate gasket space (8a,8b) of each sealing arrangement is connected to the pressure source (10) via conduits (12a,12b), and a leakage sensor (11a,11b) is located on each conduit
30 (12a,12b) between the pressure source (10) and the intermediate gasket space (8a,8b), each leakage sensor (11a,11b) being configured to continuously transmit leakage detection data to

the evaluation device (17), and the evaluation device (17) being configured to continuously receive said leakage detection data.

28. The system of claim 27, wherein the evaluation device (17) comprises a control unit (41) comprising a memory unit (42) and a processor (43) and preferably a communication means (44) arranged to be able to communicate with an external recipient (45), wherein the memory unit (42) is arranged to be able to store computer readable code that when executed on the processor (43) performs the method according to claims 16-25.

29. The system of any one of claims 26-28, wherein the confined volume (19a,19b) is a containment enclosure, comprising a housing (24) and an air inlet opening (25) into which a filter (26) is fitted, wherein the filter is sealed to the housing by means of a sealing arrangement as defined in any one of claims 1-15.

30. The system any one of claims 26-28, wherein the confined volume (19a,19b) is a cleanroom provided with an air filtration arrangement comprising a mounting structure wherein the filter (26) is sealed to the a mounting structure by means of a sealing arrangement as defined in any one of claims 1-15.

31. The system any one of claims 26-28, wherein the confined volume (19a,19b) is a pharmaceutical production space provided with an air filtration arrangement comprising a mounting structure wherein the filter (26) is sealed to the a mounting structure by means of a sealing arrangement as defined in any one of claims 1-15.

32. A computer program product arranged to perform the method according to any one of claims 16-25, when executed in a system according to any one of claims 28-31.

33. A filter housing (24) configured for mounting of an air filter (14) against a mounting structure (15, 30) comprised in the filter housing, **characterized in** that the mounting structure is configured to be used as the second element of the sealing arrangement of claims 1-15, and in that the filter housing comprises a connection (120, 121) adapted to be coupled to a pressure source (10), and being configured to connect an intermediate gasket space (8) to the pressure source, said intermediate gasket space (8) being formed between two elongated gasket members (6, 7) of a gasket (5) arranged between the mounting structure (15,30) and the filter (14).

34. The filter housing of claim 33, wherein the connection is a channel or conduit (120) arranged through the mounting structure (15, 30), and wherein a first end of the channel or conduit (120) is arranged in a position in the mounting structure that is configured to be located within the intermediate gasket space (8) when an air filter is mounted in the filter housing.

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35. The filter housing of claim 33, wherein the connection is a conduit (121) provided within the filter housing, said conduit comprising an insertion portion configured to be inserted through one of the elongated gasket members (6, 7) of a gasket (5) arranged between the mounting structure (15,30) and the filter (14); or wherein the connection is a conduit (121) comprising a connector (122) configured to be connected to a channel or conduit (12) provided in the air filter.

36. An air filter (14) for use as the first element (3) in the sealing arrangement of claim 1-15, the air filter being configured to be mounted to a filter mounting structure (15, 30) in a filter housing (24) and comprising

a filter frame (13) having an opening (25) in which an air filter media pack assembly (40) is positioned, or can be positioned, and
a gasket (5) configured to seal a gap (2) between the filter frame and the filter mounting (15, 30) structure in the filter housing (24),

characterized in that the gasket is attached to the filter frame and is arranged to surround the opening (25); and

the gasket (5) comprises two elongated gasket members (6, 7), where an inner elongated gasket member (6) is configured to surround the opening (25) where the air filter media pack assembly (40) is positioned, and an outer elongated gasket member (7) is configured to surround the inner gasket (6) and the opening (25); and

the gasket is attached to the frame so that the elongated gasket members (6,7) are held in position on a distance from each other so as to form an intermediate gasket space (8) between the gasket members (6,7) and a surface (13a) of the frame onto which the gasket is attached; and

the air filter comprises a channel or conduit (12) arranged to connect the intermediate gasket space (8) with the surroundings, and being configured to be connected to a pressure source to allow application of pressure on the intermediate gasket space (8) during use.

5 37. The air filter of claim 36, wherein the channel or conduit (12) is arranged through the filter frame, or through one of the elongated gasket member (6, 7), or is disposed on the surface (13a) of the filter frame (13) onto which the elongated gasket members are attached.

10 38. A sealing arrangement (31) comprising a gasket (35) arranged to seal a gap (32) formed between a first element (33) and a second element (34), wherein the gasket is arranged to be located in the gap (32) and to be in contact with the first and the second elements (33,34), wherein the first element is comprised in a frame (313) of a filter (314) and the second element is comprised in a mounting structure (315) against which the filter is mounted **characterised in that** the sealing arrangement includes a means (39) for continuous monitoring of sealing integrity.

15 39. The sealing arrangement of claim 38, comprising means (311) to directly detect a loss of sealing integrity.

20 40. The sealing arrangement of any one of claims 38-39 wherein the first element is comprised in a frame (313) of an air filter (340) of panel type, box type or V type and having any of the filter classes E10, E11, E12, H13, H14, U15, U16, U17 according to EN1822, or being classified according to ISO 16890.

 41. A method (300) of monitoring sealing integrity of a pharmaceutical production space, in which a production batch is produced, **characterised in that** the monitoring is performed continuously by means of leak detection (301) using the sealing arrangement of any one of claims 38-40.

25 42. The method of claim 41, comprising the step of generating a message (302) indicating leakage if a leak incident is detected, and transferring (303) said message to control unit being capable to tag said leak incident to production batch currently produced.