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OWA Faserplattenwerk GmbH
OWAtecta cleanRoom
Report No. OW 1105-554

DUPLICATE

Statement of
Qualification

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Statement of Qualification

Customer:

Odenwald Faserplattenwerk GmbH
Dr.-F.-A.-Freundt-Straße 3
63916 Amorbach
Germany

Component tested:

Category: Cleanroom Facilities

Subcategory: Wall / Ceiling / Floor

Type: OWAtecta cleanRoom
- System L
- System U

Random check measurements of particle emission (airborne) at representative points

Test procedure: According to VDI 2083 Part 9.1

Measuring instruments being used: Optical Particle Counters:
Model LasAir II 110 manufactured by PMS with measuring channels of ≥ 0.1 µm, ≥ 0.2 µm ≥ 0.3 µm, ≥ 0.5 µm, ≥ 1.0 µm and ≥ 5.0 µm

Test parameters of the test environment:
- Cleanroom of Air Cleanliness Class: ISO Class 1 (according to ISO 14644-1)
- Air flow velocity: 0.45 m/s
- Air flow guidance: vertical unidirectional air flow from ceiling to floor
- Temperature: 22 °C ± 0.5 °C (71.6 °F ± 0.9 °F)
- Relative humidity: 45 % ± 5 %

Test parameters of the test execution: The wall/ceiling system was stressed as follows:
- Impact sound: between approx. 5 Hz and 50 Hz
- Average oscillation velocity: v = 0.113 mm/s
- Average oscillation acceleration: a = 0.042 m/s²
- Average oscillation of the system: s = 0.0004 mm

Test results:
(according to ISO 14644-1)

The system OWAtecta cleanRoom is suitable for use in cleanrooms fulfilling the Air Cleanliness Class 4 according to ISO 14644-1.

Assessment of conformity with GMP regulations and EHEDG conception and design recommendations

Test procedure: According to EU GMP Annex 1; EHEDG Doc. 8; DIN EN 1672-2; ISO 14159

Test results:
(according to EU GMP Annex 1)

A principle recommendation can be made for use in hygienic areas up to a maximum of GMP Cleanliness Class A. However, this only applies for the assessed operating utility in a resting state and the OWAtecta cleanRoom system L would need to be reassessed after assembly in a manufacturing environment.

A principle recommendation can be made for use in hygienic areas up to a maximum of GMP Cleanliness Class C. However, this only applies for the assessed operating utility in a resting state and the OWAtecta cleanRoom system U would need to be reassessed after assembly in a manufacturing environment.

The measuring equipment used for the qualification is regularly calibrated and is based on national and international standards. In the case where no national standards exist, the measuring procedure used corresponds with technical regulations and norms valid at the time of the measurement. The documents drawn up for this procedure are available for viewing.

The validity of this certificate applies only to the mentioned product in this particular condition. Further information: **www.tested-device.com**.

Fraunhofer Institute for
Manufacturing Engineering and Automation IPA

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and Micromanufacturing

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Stuttgart, August 22, 2011
Place, Date

i. A.
Project manager

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