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**TESTED[®]
DEVICE**

DYNACO
D-313 CLEANROOM LF
Report No. DY 1203-590

DUPLICATE

Statement of
Qualification

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Customer: DYNACO Europe N.V.
Waverstraat 21
9310 Moorsel (Aalst)
Belgium

Component tested:

Category: Cleanroom Facilities
Subcategory: Wall / Ceiling / Floor
Type: D-313 CLEANROOM LF

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 Counter:

- Model LasAir II 110 manufactured by PMS with measuring channels of $\geq 0.1 \mu\text{m}$, $\geq 0.2 \mu\text{m}$, $\geq 0.3 \mu\text{m}$, $\geq 0.5 \mu\text{m}$, $\geq 1.0 \mu\text{m}$ and $\geq 5.0 \mu\text{m}$
- Model Airnet 310 manufactured by PMS with measuring channels of $\geq 0.3 \mu\text{m}$, $\geq 0.5 \mu\text{m}$, $\geq 1.0 \mu\text{m}$ and $\geq 5.0 \mu\text{m}$

Test parameters of the test environment:

- Cleanroom Air Cleanliness Class (according to ISO 14644-1):..... ISO 1
- Air flow velocity:..... 0.45 m/s
- Air flow guidance:vertical unidirectional air flow
- Temperature: 22 °C \pm 0.5 °C (71.6 °F \pm 0.9 °F)
- Relative humidity: 45 % \pm 5 %

Test parameters of the test execution:

- Clear distinction made between clean side and side of the driving mechanism
- (Maximum) opening speed: 2.7 m/s
- (Maximum) closing speed: 0.5 m/s
- Max. dimensions: 3500x3500 mm
- Tested dimensions: 2000x3000 mm
- Leak tightness (acc. to EN 12426): Class 3 (over-/underpressure)

Test results / Classification:
(according to ISO 14644-1)

Both the clean side of the D-313 CLEANROOM LF as well as the side of the driving mechanism are suitable for use in cleanrooms fulfilling Air Cleanliness Class 6.

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 / Classification:
(according to: EU GMP Annex 1)

Both sides of the D-313 CLEANROOM LF are principally recommended for use in hygienic areas up to GMP Class C. However, this only applies for the assessed operating utility in a resting state and the recommendation needs to be reconsidered once the devices have been installed into a production line.

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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 for a duration of 5 years.
Further information: www.tested-device.com.

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Stuttgart, April 27, 2012
Place, Date


i. A.
Project manager