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DEVICE

HAMILTON Bonaduz AG
Microlab STAR
Report No. HA 1201-587

DUPLICATE

Statement of
Qualification

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Statement of Qualification

Customer:

HAMILTON Bonaduz AG
Via Crusch 8
7402 Bonaduz
Switzerland

Component tested:

Category: Automation Components

Subcategory: Robotics

Type: Microlab STAR

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

Test procedure:
The test procedure implemented regarding airborne particle measurements was only performed on the basis of guideline VDI 2083 Part 9.1:
- Inspection of the system
- Positioning of the measurement probes (four probes used) at freely-chosen sites
- Testing time: 2h
- Number of measurement values analyzed: 100

Measuring instruments:
Optical Particle Counter:
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 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 ± 0.5 °C (71.6 °F ± 0.9 °F)
- Relative humidity: 45 % ± 5 %

Test parameters of the test execution:
- Process simulation imitates routine aseptic manufacturing process with all critical subsequent manufacturing steps.
- Number of runs: 4
- Duration (total run): 27 min 40 s

Test results / Classification:
(according to ISO 14644-1)
The tests on the Microlab STAR were carried out based on guideline VDI 2083 Part 9.1 and showed a non-conform suitability for use in cleanrooms class 4. However, a clear suitability of the system cannot be declared.

Particulate product contamination based on PWP* particle emission measurements (sedimented) on silicon wafers

Test procedure: According to ITRS 2001

Measuring instruments: Surface scanner KLA-Tencor Surfscan 6200 with the particle size range 0.07 µm - 64 µm

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 ± 0.5 °C (71.6 °F ± 0.9 °F)
- Relative humidity: 45 % ± 5 %

Test parameters of the test execution:
- Process simulation imitates routine aseptic manufacturing process with all critical subsequent manufacturing steps.
- Number of runs qualification cycle 1: 71
- Number of runs qualification cycle 2: 74
- Duration (total run): 27 min 40 s

Test results / Classification:
(PWP criteria ITRS 2001: 1×10^{-3} PWP/cm² for particle sizes > 0.075 µm)
- 1.4×10^{-3} PWP/cm² (Particle 0.21 µm - 7.70 µm)
- 1.1×10^{-3} PWP/cm² (Particle 1.40 µm - 6.30 µm)

Based on PWP measurements, no risk of particulate product contamination is detected according to Ph. Eur. 2.9.19.

*PWP corresponds with Particles per Wafer Pass

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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and Micromanufacturing

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Stuttgart, September 28, 2012
Place, Date

i. A.
Project manager

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