



Fraunhofer

TESTED[®] DEVICE

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

DUPLICATE

Statement of
Qualification

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Customer: HAMILTON Bonaduz AG
Via Crusch 8
7402 Bonaduz
Switzerland

Component tested:

Category: Automation Components
Subcategory: Robotics
Type: Microlab STAR
Equipment:

- Liquid handling robot:
ML-STAR, manual load, modular arm 96, 16 channel on modular arm:
1000 µl, serial number 4121
- Sterile tips:
IVD compliant, filling volume: 1000 µl, γ-sterilized, part number 235 905
- Polystyrene multiwell plates:
CELLSTAR 96 well suspension culture plate with lid, exposed surface area
of one well: 0.35 cm², transparent and sterile, No. 650 185, Greiner Bio-
One GmbH
- Media storage container:
Thermo Nunc 300 ml reservoir, Thermo Scientific, flat, non-sterile,
disposable, No. 370 905, exposed surface area: 96 cm²
- PCA plates:
Sterile Plate count-agar settle plates, No. 1.13108.0001, Merck KGaA
- Settle plates:
Sterile TSA contact blister TLHTh double wrap, diameter: 55 mm, Tryptic
Soy with neutralizers, REF 251114TI, BDH Prolabo, VWR International

Test environment:

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 %

Media fill simulation

Test procedure: According to EU GMP guideline Annex 1
Test parameters of the test execution:

- Process simulation imitates routine aseptic manufacturing process with
all critical subsequent manufacturing steps.
- Number of wells:.....5472

- Number of runs:.....19
- Duration (total run):.....27 min 13 s

Test results / Classification:
(according to EU GMP guideline Annex 1)

The Microlab STAR in principle fulfills the criteria for a successful media fill simulation for aseptic processing.

Remark: After installation in an aseptic production line, a media fill with all parameters of the later used procedure is still necessary.

Simulation of microbiological product contamination

Test procedure: According to ISO 14698-1 and -2
Test parameters of the test execution:

- Process simulation imitates routine aseptic manufacturing process with
all critical subsequent manufacturing steps.
- Number of PCA plates:.....20
- Number of runs:.....4
- Duration (total run):.....27 min 40 s

Test results / Classification:
(according to EU GMP guideline Annex 1)

The Microlab STAR in principle fulfills the criteria for a safe aseptic processing.

Air flow visualization

Test procedure: According to EU GMP guideline Annex 1
Test parameters of the test execution:

- Process simulation imitates routine aseptic manufacturing process with
all critical subsequent manufacturing steps.
- Operation:..... removed roofing

Test results / Classification:
(according to EU-GMP guideline Annex 1)

During operation the primary laminar airflow direction was maintained the whole time. The influence of the robot arm of the Microlab STAR was acceptable. No influence from personnel could be observed.

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, September 28, 2012
Place, Date


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Project manager