



**Fraunhofer**

**TESTED<sup>®</sup>  
DEVICE**

Bettinelli F.lli S.p.A.  
Rotary part handler MRE80  
**Report No. BE 1202-588**

DUPLICATE

Statement of  
Qualification

# Statement of Qualification

**Customer:** Bettinelli F.Ili S.p.A.  
Via Leonardo da Vinci  
26010 Bagnolo Cremasco  
Italien

## Component tested:

Category: Automation Components  
Subcategory: Transfer Systems and Bearing  
Type: Rotary part handler MRE80

## 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:

- Load:..... 10 kg
- Vertical motion
  - Vertical stroke:..... 40 mm
  - Lifting time t:..... 0.06 s
  - Lifting speed v: ..... 645 rpm
- Rotation
  - Angular rotation: ..... 90 °
  - Rotation time t: ..... 0.06 s
  - Rotation speed v:..... 1000 rpm

**Test results / Classification:**  
(according to ISO 14644-1) The rotary part handler MRE80 is suitable for use in cleanrooms fulfilling Air Cleanliness Class 2.

## 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)

The rotary part handler MRE80 can in principle be declared suitable for use in hygienic areas at GMP Cleanliness Class D zones. However, this only applies for the tested operating utility when in a resting state and an overall reassessment would need to be made after installation in a manufacturing environment.

DUPLICATE

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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](http://www.tested-device.com).


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Stuttgart, October 5, 2012

Place, Date

  
i. A.   
Project manager