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TESTED[®] DEVICE

Bettinelli F.lli S.p.A.
Precision link conveyor TL75
Report No. BE 1202-588

DUPLICATE

Statement of
Qualification

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

Component tested:

Category: Automation Components
Subcategory: Transfer Systems and Bearing
Type: Precision link conveyor TL75

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

Test procedure: According to VDI 2083 Part 9.1

Measuring instruments: 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:

- Number of links:.....28
- Link weight: 1.0 kg
- Aluminium piece holder weight:..... 0.9 kg
- Velocity v_{max} : 160 mm/s
- Acceleration a_{max} : 10000 mm/s²

Test results / Classification:
(according to ISO 14644-1) The precision link conveyor TL75 is suitable for use in cleanrooms fulfilling Air Cleanliness Class 7.

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 precision link conveyor TL75 does not fulfill the requirements of clean and hygienic manufacturing. However, if all the optimization potentials recommended are carried out, it is possible that the conveyor could become suitable for use in clean and hygienic manufacturing conditions.

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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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Place, Date


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