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DEVICE

Cleanroom Laboratory
Report No. NY 0211-282

Certificate of
qualification

Fraunhofer Institut
Produktionstechnik und
Automatisierung

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Automatisierung

Qualifizierungsbescheinigung
Certificate of qualification

Manufacturer of object to be tested:

N.Y.R. Limited Partnership
159 Charansanitwong Rd.
Bangkok 10700, Thailand

Component tested:

Cleanroom laboratory at the Silpakorn University, Nakornpathom

Test parameters of object to be assessed:

Cleanroom laboratory in operation

Performed tests:

Measurement of particle emission and air flow velocity at representative points (according to ISO 14644-1 and EU GMP-Guideline)
Measurement of pressure difference between laboratory compartments and outside world
Air flow assessment via air flow visualization
Leakage tests

Test results/classification:

The biosafety cleanroom laboratory installed by N.Y.R. Limited Partnership at the Silpakorn University, Nakornpathom, is suitable for operations that are depending on a P3 laboratory according to guideline M 057 BG Chemie.

- The above mentioned cleanroom laboratory is fulfilling the specifications of Class 6 according to EU GMP-Guideline vol. 4, annex 1
- Pressure difference between laboratory compartments and outside world:
  Pressure laboratory to grey room: - 30 Pa
  Pressure laboratory to air lock: 45 Pa
- Air flow visualization shows an overall even distribution of air flow in the cleanroom

Standards used for the qualification:

ISO 14644-1
Guideline M 057 BG Chemie

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

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Fraunhofer-Institut
für Produktionstechnik
und Automatisierung IPA

Abteilung Reinst- und Mikroproduktion
Department Cleanroom Manufacturing

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Stuttgart, November 7th, 2002
Ort, Datum
Place, date

i.A.
Unterschrift Bearbeiter
Signature of person responsible