



Fraunhofer

TESTED DEVICE

Cleanroom Laboratory
Report No. NY 0003-170

Certificate of
Qualification

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 Faculty of Medicine, Siriraj Hospital, Bangkok

Testparameters of object to be assessed:

Cleanroom laboratory in operation

Performed tests:

Measurement of particle emission and air flow velocity at
representative points (according to US Fed. Standard 209E)
Measurement of pressure difference between laboratory
compartments
Air flow assessment via air flow visualization
Leakage tests

Test results/classification:

The cleanroom laboratory installed by N.Y.R. Limited Partnership
at the Faculty of Medicine, Siriraj Hospital, Bangkok, 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 Cleanliness Class 100.000 according
to US Fed. Standard 209E.
- Pressure difference between laboratory compartments
and outside world:

Pressure laboratory / grey room: -100 Pa
Pressure laboratory / air lock: 30 Pa

- Air flow visualization shows an overall even distribution
of air flow in the cleanroom
- Air flow visualization shows leakage at the sealing of UV
material lock

Standards used for the qualification:

ISO 14644 -1
US Federal Standard 209E
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.

Fraunhofer Institut
für Produktionstechnik
und Automatisierung

Abteilung Mikroproduktion
Department Cleanroom Manufacturing

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Place, date: Unterschrift Bearbeiter

Signature of person responsible