# Fraunhofer TESTED® DEVICE

N.Y.R. Biological Safety
Cleanroom Laboratory
Report No. NY 0512-339

---

Statement of
Qualification



Fraunhofer Institut
Produktionstechnik und
Automatisierung

Fraunhofer Institut
Produktionstechnik und
Automatisierung

# Statement 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 Chulalongkorn University, Bangkok

**Test parameters of object to be assessed:**

Biological Safety Cleanroom Laboratory in operation

**Performed tests:**

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

**Test results/classification:**

The Biological Safety Cleanroom Laboratory installed by N.Y.R. Limited Partnership at the Chulalongkorn University, 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 Air Cleanliness Class 7 according to ISO 14644-1 (class 10000 according US Federal Standard 209E).
- Pressure difference between laboratory compartments and outside world: Pressure laboratory: -30 Pa
- Air flow visualization shows an overall even distribution of air flow in the cleanroom
- Air flow visualization shows no leakage
- The number of measured particles corresponds with Class C according the current EG-GMP guideline
- The air distribution inside the biological cleanroom has been strongly improved by modification of the air inlets

**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
Produktionstechnik und
Automatisierung

Fraunhofer-Institut
für Produktionstechnik
und Automatisierung IPA

Abteilung Reinst- und Mikroproduktion
Department Cleanroom Manufacturing

Nobelstrasse 12
D-70569 Stuttgart

Stuttgart, Germany, 07th December 2005
Place, date

Udo Sonnenberg
Signature of person responsible