Fraunhofer
IPA

FRAUNHOFER INSTITUTE FOR
MANUFACTURING ENGINEERING AND AUTOMATION IPA

# QUALIFICATION – CERTIFICATION OF EQUIPMENT, DEVICES AND CONSUMABLES


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## Introduction

An increasing number of products needs to be manufactured in highly clean environments. Even tiny amounts of contamination during the production process are enough to cause significant losses or damage. As a result, the demand for machines, devices, materials and production utilities which are suitable for use in cleanrooms is constantly increasing.

This trend is being especially observed in the following industries:

- Semiconductor manufacturing
- Microsystem production
- Medical technology and pharmacy
- Food technology
- Precision engineering
- Optical industry
- Display production
- Photovoltaics

## Cleanliness quality and forms of contamination

The market demand for the cleanliness-related properties of all operating utilities to be assessed both practically and reliably is increasing. Cleanliness suitability and cleanroom suitability are decisive technical features.

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The following elements are considered as being potential sources of contamination and therefore require testing:

- Automation equipment
- Manufacturing and process devices
- Measurement and testing equipment
- Transport systems
- Fittings
- Consumables
- Supply and disposal components (media, semi-finished parts, etc.)

Quality management regulations required either by authorities or customers (e. g. ISO 9000 ff., GMP) also demand a comprehensive and complete qualification of the manufacturing processes implemented, from the planning stage right up to the point of goods issue.

## Qualification methods and standards

The basis used to qualify operating utilities, materials and production environments is formed by cleanliness requirements and the resulting specifications for the product to be manufactured. In the process, a wide range of contaminants may have a negative influence on the product concerned:

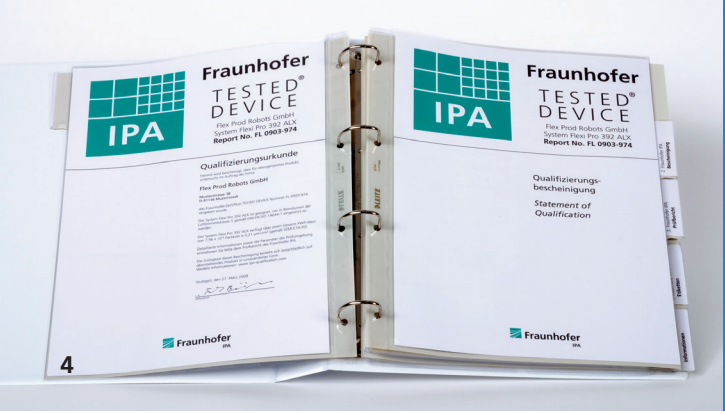
- Particles
- Outgassing
- ESD characteristics

- Germs, bacteria
- Electromagnetic fields
- Molecular contamination
- Vibrations, etc.

In order to be able to compare classification results, it is essential that a defined, standardized practice using test procedures, which have been methodically proven, is implemented when carrying out cleanliness tests.

- ISO 14644-1 (US Fed. Standard 209E)
- IES-RP (Institute of Environmental Sciences – Recommended Practices)
- ASTM (American Society for Testing and Materials)
- US Military Standard 1246
- VDI-Richtlinien
- DIN and ISO Standards
- SEMI/SEMATECH Standards
- EG GMP
- ISO 14644-8
- VOI 2083 Sheet 9.1, 9.2 and 17

**1** *Test device for detecting particles.*
**2** *Classification tests on lighting systems.*
**3** *Consumables.*




Where no standards or practices exist for certain qualification tasks, the Fraunhofer IPA develops its own methodically-sound procedures using the experience and knowledge it has gained over many years. The institute has a broad spectrum of know-how at its disposal which it utilizes to implement cleanliness concepts in all fields of manufacturing.

## Documentation

The results of the qualification or certification performed are presented in the form of test seals, certificates and statements as well as detailed test reports.

## Data base

After the successful certification of a product the results are being collected in a worldwide unique internet-based data base. This enables our project partners not only to access online their results and contact details, but also if desired, to publish it for public use (e. g. research, marketing purposes): **www.tested-device.de.**

**TITLE** *Heavy duty ISO Class 1 cleanroom.*

**4** *Detailed documentation of test results.*

## Our service profile

We offer the following assessment, development and optimization services as well as marketing activities:

- Sector-orientated consulting
- Identification of relevant tests and consumables
- Certification of devices, components and equipment for clean applications
- Certification of manufacturing environments and products in accordance with cleanliness requirements
- Certification and development of measurement and testing procedures for controlling cleanliness
- Identification of optimization potentials
- Provision of customer and market orientated documentation:
  – Test logo
  – Certificates
  – Statements
  – Detailed test reports
  – Electronic data files

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For further information about our range of services, solutions and consultancy, please contact our experts.

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