

FRAUNHOFER IPA CERTIFICATION TESTED DEVICE® & CSM®

Develop, ensure, communicate quality



CONTENTS

1. Assignments of cleanliness technology
 2. Industrial branches and cleanliness criteria's
 3. Product protection
 4. Test objects and categories
 5. Cleanliness and Cleanroom suitability
 6. National and international guidelines
 7. Performance of the particle emission test (example: robot)
-
8. Fraunhofer TESTED DEVICE® and CSM®
 9. Certification process
 10. Contents of the certification folder
 11. Impressions of the certification documents
 12. Database TESTED DEVICE®
 13. Benefits for the customer

*» To determine the suitability of machinery and equipment
for use in cleanrooms (ISO 14644),
Fraunhofer IPA performs tests in accordance with ISO 14644-14. «*



Assignments of cleanliness technology

Personal protection

Protection of Persons regarding the influence of harmful Dust particles, germs or bacterias.

ASSIGNMENTS OF CLEANLINESS TECHNOLOGY

Protection of products regarding the influences of contamination of any type.

Product protection



Product protection

factors affecting product quality



Test objects and categories

Automation components	Transfer systems and bearings	Process equipment	Work benches
	Linear units		Wafer equipment
	Robotics		Pneumatic components
	Positioning systems		Vacuum components
Cleanroom facilities	Wall / door		Heating and cooling
	Ceiling / floor		Measuring equipment
	Air conditioning systems		Circuit board assembly
	Lighting systems		Sorting and packaging
	Filtration systems	Production environment	Cleanroom acceptance
	ESD control		Process evaluation
Materials	Plastics		Production lines
	Lubricants / sealants / adhesives	Working place and operator	Chairs
	Consumables		Work equipment
	Liquids		Storage
	Coatings		Equipment parts
	Material composites		Garments
	Metals	Energy supply	Cable systems
	Ceramics		Cable guiding systems
	Packing materials		

Industrial branches and cleanliness criterias

	Particle emission	Outgassing VOC / SVOC	Outgassing anions	Outgassing NH ₃	ESD	Cleanability (Riboflavin test)	Chemical resistance	Biological resistance	Antibacterial activity	H ₂ O ₂ absorption / desorption	Hygienic Design
Semiconductor industry	++	++	+	+	++	+	+	+	0	0	0
Electronic	++	+	+	+	++	0	0	0	0	0	0
Display (e.g. mobile phone)	++	+	0	0	++	0	0	0	0	0	0
Battery technology	++	0	0	0	++	0	0	0	0	0	0
Microsystem technology	++	+	0	0	++	+	+	+	0	0	0
Optic	+	++	+	+	+	+	+	+	0	0	0
Photovoltaic	+	+	0	0	+	0	0	0	0	0	0
Aerospace	++	++	+	+	++	+	+	+	+	0	0
Pharmacy	++	0	0	0	+	++	++	++	++	++	++
Biotechnology	+	+	0	0	0	++	++	++	++	+	++
Medical technology	+	0	0	0	+	++	++	++	++	+	++
Food technology	+	0	0	0	0	++	++	++	++	+	++
Hospital	0	0	0	0	0	++	++	++	++ ^{*)}	+	++

^{*)}depending on the subject

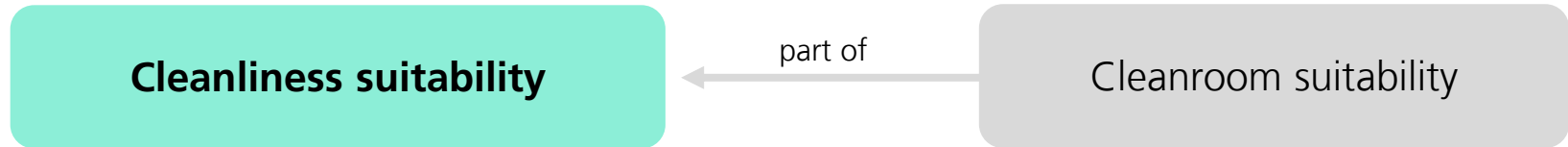
Legend: ++ mandatory | + recommended, but not mandatory | 0 generally not required but in individual cases recommended

Air Cleanliness Classes according to ISO 14644-1

Regulatory				Limiting values of each air cleanliness class for differing particle sizes and reference volumes (acc. to ISO 14644-1)											
EG-GMP "in operation "	EG-GMP "at rest"	US Fed. Standard 209E*	DIN EN ISO 14644-1	0.1 µm		0.2 µm		0.3 µm		0.5 µm		1.0 µm		5.0 µm	
				per m³	per cbf	per m³	per cbf	per m³	per cbf	per m³	per cbf	per m³	per cbf	per m³	per cbf
			1	10	0,3										
			2	100	3	24	1	10	0,3						
		1	3	1.000	30	237	7	102	3	35	1				
				1.240	35	265	8	106	3	35	1				
		10	4	10.000	300	2.370	67	1.020	29	352	9,9	83	2		
				12.000	340	2.650	75	1.060	29	353	10				
A	A	100	5	100.000	2.833	23.700	671	10.200	289	3.520	100	832	24	29	0,8
										3.520	100			20	0,6
										3.520	100			20	0,6
										3.520	100			29	0,8
						26.500	750	10.600	300	3.530	100				
		1.000	6	1.000.000	28.329	237.000	6.710	102.000	2.890	35.200	997	8.320	235	293	8
										35.300	1.000			247	7
B	C	10.000	7							352.000	9.972	83.200	2.357	2.930	83
										352.000	9.972			2.900	82
										352.000	9.972			2.900	82
										353.000	10.000			2.470	70
C	D	100.000	8							3.520.000	99.716	832.000	23.569	29.300	830
										3.520.000	99.716			29.000	821
										3.520.000	99.716			29.000	821
										3.530.000	100.000			24.700	700
			9							35.200.000	997.167	8.320.000	235.694	293.000	8.300

Cleanliness suitability

Definition



- **Cleanliness suitability** of machinery/Equipment includes all relevant cleanliness criteria's for an effective process
- Criteria's of the cleanliness suitability are e.g.:

■ Particle emission	■ Antibacterial activity	■ ESD
■ Chemical resistance	■ Outgassing behavior	■ Hygienic design/ GMP-conformity
■ Biological resistance	■ Riboflavintest	
- The customer gets an qualification package for every tested product from Fraunhofer IPA

Cleanroom suitability

Definition

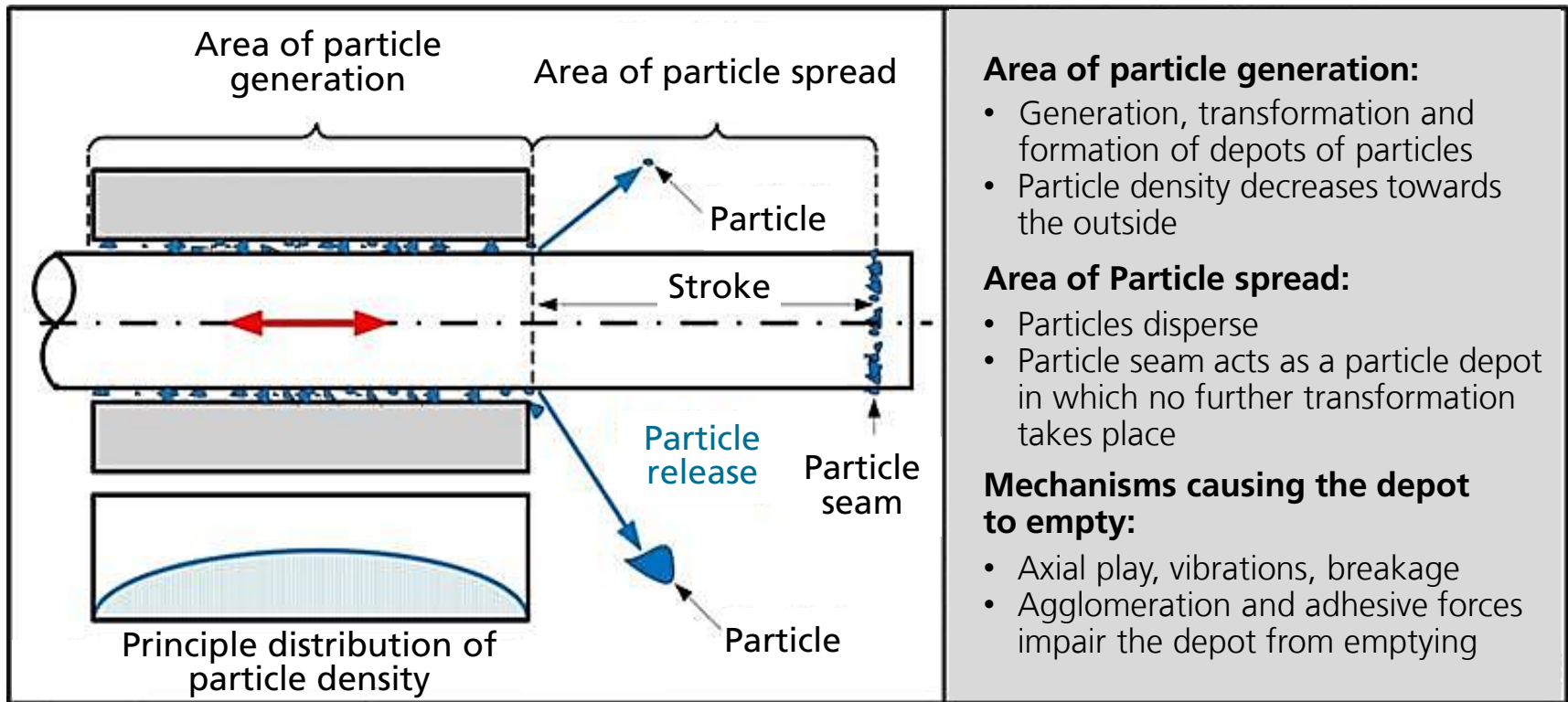


- **Cleanroom suitability** is one of the most important criteria's regarding clean or hygienic industrial areas
- **Cleanroom suitability** describes the emission behavior of particles
- Main reason for particle emission in machinery/equipment is tribological stress



Example: Linear slide bearing

Friction ► wear ► particle generation ► particle release



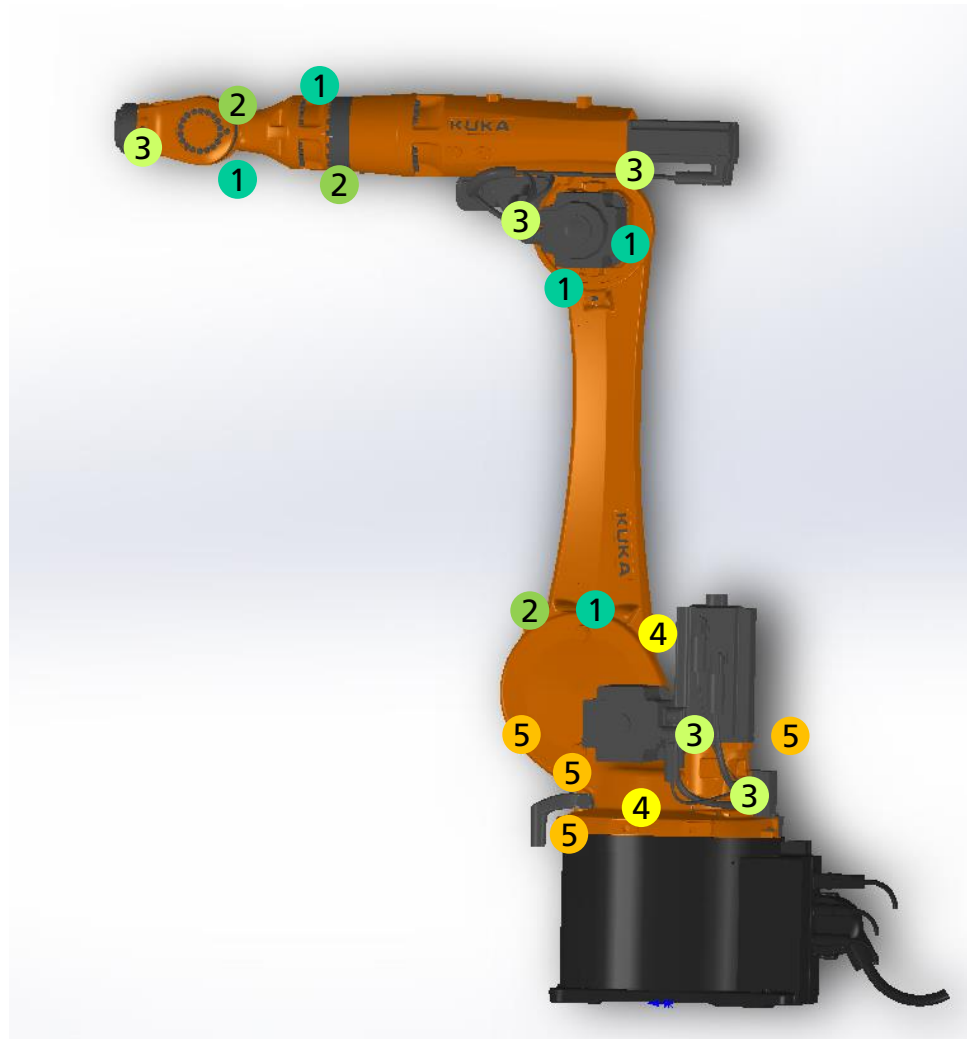
Quelle: Dr.-Ing. Bürger (2017)

National and international guidelines

- **Proof of compliance with cleanroom and cleanliness suitability requirements** according to national and international guidelines
- Guidelines includes approaches regarding the examination, requirements of the measurement area and measuring instruments, classification systems and evaluation standards

Cleanliness criterias (examples)	guidelines
Classification of air quality (cleanroom quality)	ISO 14644-1
Determination of cleanroom suitability (particle)	ISO 14644-14
Determination of outgassing behavior	ISO 14644-15
Determination of chemical resistance	ISO 2812-1 u. -4
Determination of biological resistance	ISO 846
Determination of absorption/desorption von H ₂ O ₂	VDI 2083 Part 20

Performance of the particle emission test (example: robot)



Suitability for ISO 14644-1 (Air Cleanliness Class)	Measuring points
1	5 x
2	3 x
3	5 x
4	2 x
5	4 x
6	
7	
8	
9	

Total result:
suitable for ISO Class 5
(worst case consideration)

Fraunhofer TESTED DEVICE® und CSM® (Cleanroom Suitable Materials) 1/2

- TESTED DEVICE® Logo exist since 1998
- Registered trademark (DPMA)
- **International customers**
 - Customer based in 30 different country's
 - Europe \approx 70 %
 - Korea / Japan / USA / China \approx 30%
- **> 2700 tested products and materials** concerning the cleanliness and cleanroom suitability
- **Sales cooperation** with VDE-Korea for the increasing market in South Korea



Fraunhofer TESTED DEVICE® und CSM® (Cleanroom Suitable Materials) 2/2

- **Single and series/type certification**
- **State of the art measurement technology**
- **> 60 different testing procedures**
- **Cleanest cleanroom in the world**
 - 10 times better than ISO Class 1 according to ISO 14644-1
 - 6 m ceiling height
 - 5 t/m² base load capacity
- **Clean packaging of test objects after the certification**



Certification process

1/2

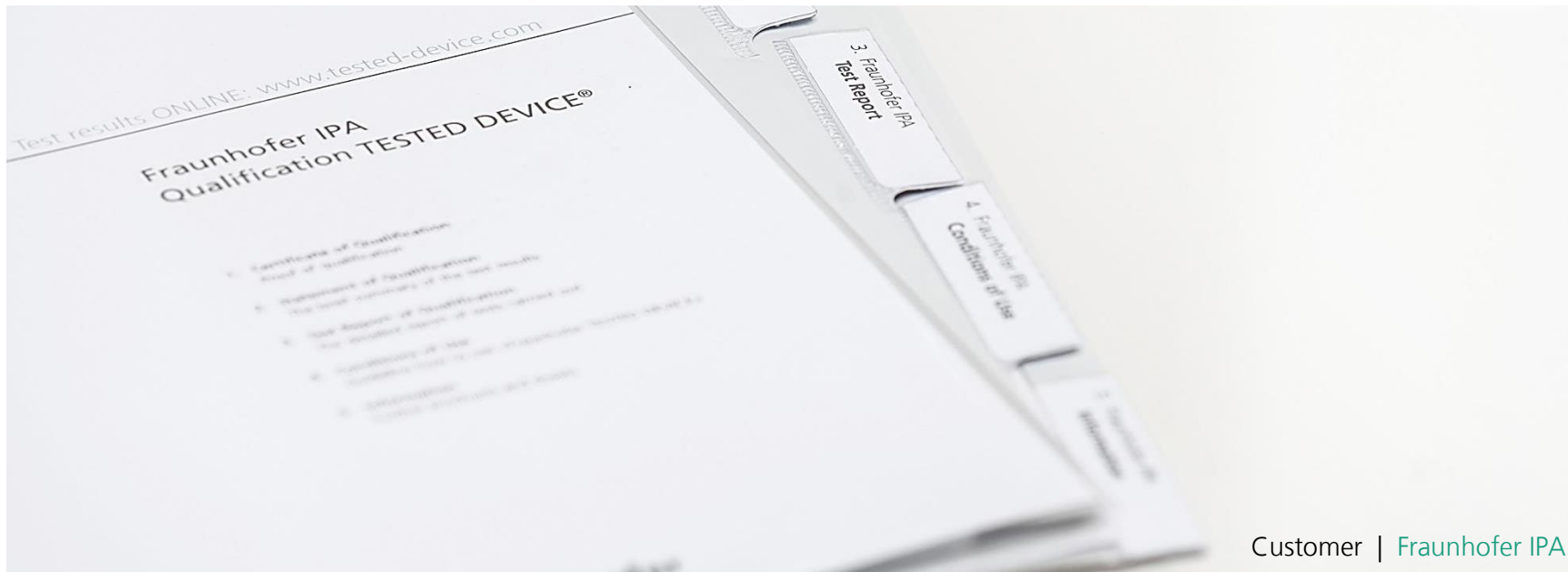
- 1) **Customer consultation** (meeting, eMail, skype, etc.)
- 2) **Product information to Fraunhofer IPA**
- 3) **Creating of an individual proposal**
- 4) **Order** (fulfilled "order of attachment" ▶ Fraunhofer IPA)
- 5) **Sending test piece(s) to Fraunhofer IPA** (Nobelstrasse12, 70569 Stuttgart, Germany)
- 6) **Measurements in the Fraunhofer IPA cleanroom lab**
 - Preparation
 - Performance
 - Analyses
 - Results ▶ if necessary: *information to customer (e.g. optimization potentials) ▶ discussing ▶ further steps*

Customer | Fraunhofer IPA

Certification process

2/2

- 7) **Pick up test piece(s) of Fraunhofer IPA**
- 8) **Creating and dispatching of documentation**
- 9) **Publication of results in the Fraunhofer IPA database** (if desired)
 - ▶ www.db.cleanmanufacturing.fraunhofer.de



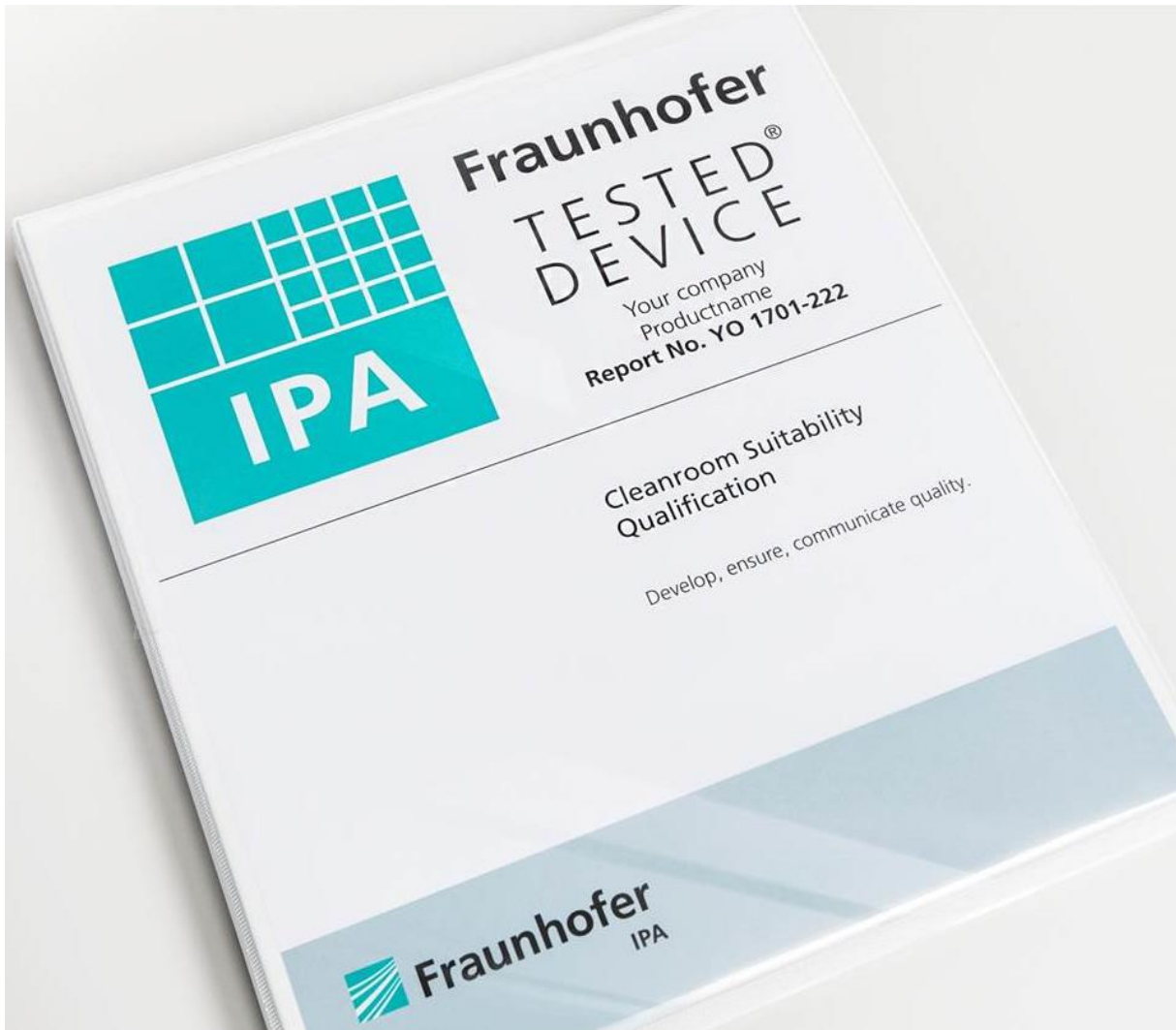
Customer | Fraunhofer IPA

TESTED DEVICE ® and CSM®

Contents of the certification folder

- **Product logo:**
individual report number ► allows traceability
- **Test report:**
detailed information (Product information, test installation, standards, etc.)
- **Certificate:**
Overview of test results
- **Statement:**
sum of all test parameters and test results (more detailed)
- **USB-stick:**
includes all digital files
- **Publishing in our database (if desired)**

Impressions TESTED DEVICE®



Impressions TESTED DEVICE®



Impressions CSM® – Cleanroom Suitable Materials



Impressions CSM® – Cleanroom Suitable Materials



TESTED DEVICE® & CSM® – Cleanroom Suitable Materials



Database* TESTED DEVICE®

LOGIN / MEIN ACCOUNT REINHEITSTECHNIK PORTAL










Fraunhofer IPA HOME UNTERNEHMEN TESTED DEVICES

Fraunhofer IPA TESTED DEVICE DATENBANK

Qualifizierung von Anlagen und Equipment für den Einsatz in Reinräumen.

TESTED DEVICE DATENBANK DURCHSUCHEN SUCHEN

Durchsuchen Sie die
TESTED DEVICE® Datenbank nach Kategorie.

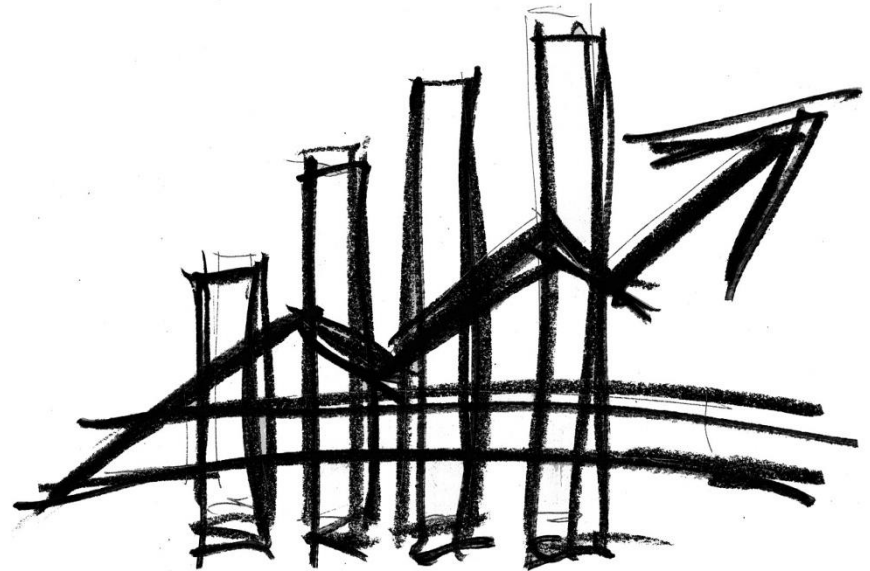
 Kabelführungssysteme	 Kabelsysteme	 Stühle
 Verbrauchsmaterialien	 Beleuchtungssysteme	 Roboter
 Transfersysteme und Lager	 Waferhandhabung	 Wände / Decken/ Böden

ALLE GETESTETEN OBJEKTE
Alle getesteten Objekte in einer Übersicht.

ANZEIGEN

TESTED DEVICE and CSM Benefits for the customer 1/2

- **Strengthens the market position**
- **Differentiation to the competitors**
- **Quality label**
 - Independent institute
- **Effective marketing element**
 - Use for advertising purposes



TESTED DEVICE and CSM Benefits for the customer 2/2

■ Analyses of weak points

- Improvement and optimization of products
- Knowledge growth
- Adaptation to individual customer requirements
- Quality increase
 - ▶ enter new market segments



Contact

Fraunhofer Institute for Manufacturing Engineering and Automation IPA
Department Ultraclean Technology and Micromanufacturing

Dr.-Ing. Frank Bürger | Phone +49 711 970-1148 | frank.buerger@ipa.fraunhofer.de

M.Sc. Jasmin Mettmann | Phone +49 711 970-1335 | jasmin.mettmann@ipa.fraunhofer.de



Adress:

Nobelstrasse 12, 70569 Stuttgart, Germany

Website:

www.ipa.fraunhofer.de/cleanroom

www.ipa-qualification.com

www.tested-device.de