



valid until: December 13, 2029

**Fraunhofer**

**TESTED  
DEVICE**

Company XY  
Robot 123

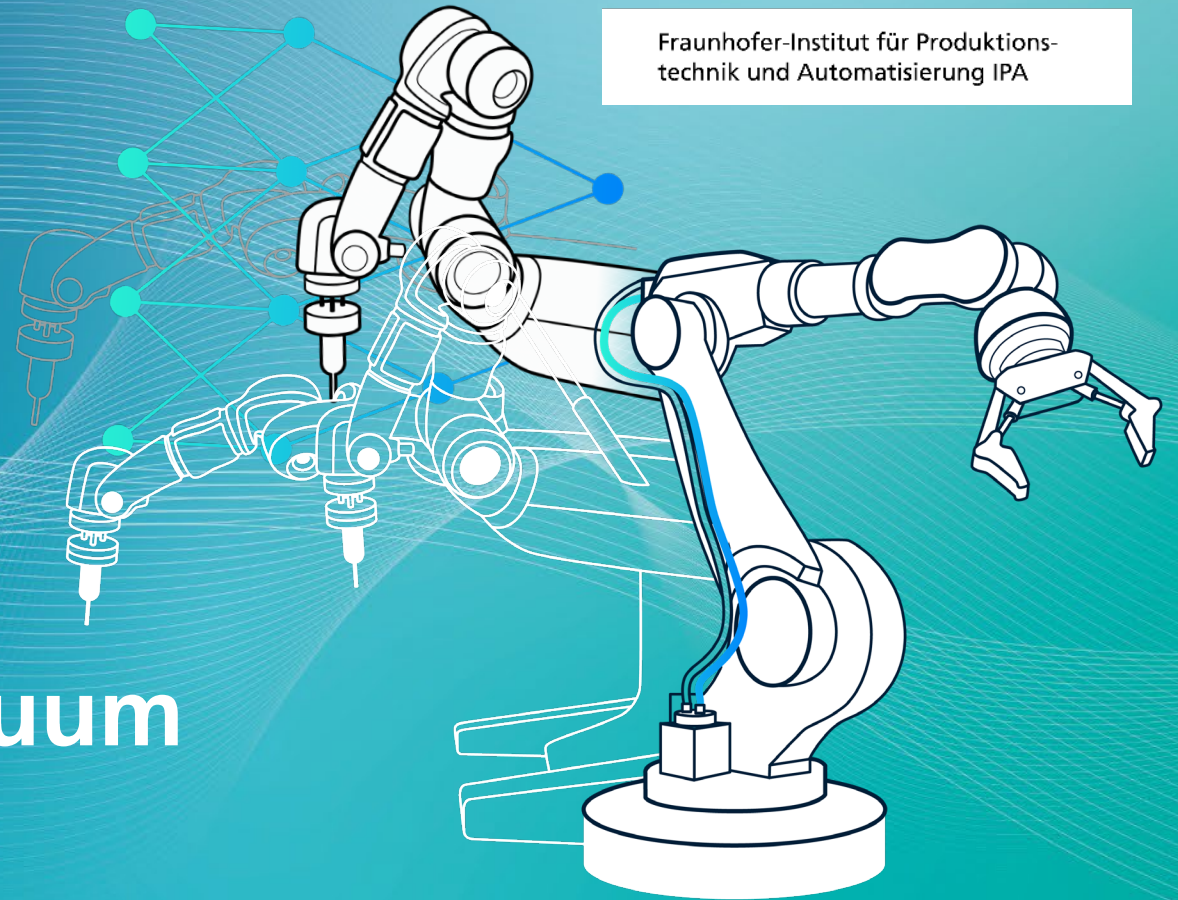
Report No. CO 1408-1456



Fraunhofer-Institut für Produktions-  
technik und Automatisierung IPA

# Equipment Certification Cleanroom, Dry-Room, Vacuum **TESTED DEVICE**<sup>®</sup>

Develop, ensure and communicate quality



# Business unit Testing & Certification, business segment Cleanliness

Determination of cleanliness suitability and cleanroom suitability



*“To determine the suitability of systems/equipment for production areas with cleanliness requirements (ISO 14644 series, etc.), Fraunhofer IPA carries out various tests in accordance with national and international regulations.”*

# Industry products and categories – TESTED DEVICE® Database

## Overview

<b>Automation Components</b>	Transfer systems and bearings	<b>Process Equipment</b>	Work Benches	
	Linear units		Wafer equipment	
	Robotics, automated guided vehicle (AGV), etc.		Pneumatic components	
	Positioning systems		Vacuum components	
<b>Cleanroom Facilities</b>	Wall / ceiling / floor / door		<b>Production Environment</b>	Heating and cooling
	Air conditioning systems			Measuring equipment
	Lighting systems			Circuit board assembly
	Filtration systems			Sorting and packaging
	ESD control			Cleanroom acceptance
<b>Materials</b>	Plastics		<b>Working Place and Operator</b>	Process evaluation
	Lubricants / sealants / adhesivs	Production lines		
	Consumables	Chairs		
	Liquids	Work equipment		
	Coatings	Storage		
	Material composites	Equipment parts		
	Metals	Garments		
	Ceramics	<b>Energy Supply</b>	Cable systems	
	Packing materials		Cable guiding systems	
		<b>Digital Testing</b>	Airflow	
			Particles	

# Industrial branches and cleanliness criterias

## Requirements

	Particle emission (cleanroom)	Particle emission (dry-cleanroom)	Particle emission (vacuum)	Outgassing VOC / SVOC	Outgassing anions	Outgassing NH <sub>3</sub>	ESD (electrostatic discharge)	Cleanability (Riboflavin test)	Chemical resistance	Biological resistance	Antibacterial activity	H <sub>2</sub> O <sub>2</sub> absorption / desorption	Hygienic design	Airflow (Digital Testing)
Semiconductor	++	0	++	++	+	+	++	+	+	+	0	0	0	++
Electronic	++	0	0	+	+	+	++	0	0	0	0	0	0	+
Display (e.g. mobile phone)	++	0	++	+	0	0	++	0	0	0	0	0	0	++
Battery	+	++	0	0	0	0	++	0	0	0	0	0	0	++
Microsystems	++	0	0	+	0	0	++	+	+	+	0	0	0	+
Optic	++	+	++	++	+	+	+	+	+	+	0	0	0	++
Photovoltaic	+	0	+	+	0	0	+	0	0	0	0	0	0	+
Aerospace	++	++	++	++	+	+	++	+	+	+	+	0	0	++
Pharmacy	++	0	0	0	0	0	+	++	++	++	*)	++	++	++
Biotechnology	+	0	0	+	0	0	0	++	++	++	*)	+	++	+
Medical	+	0	0	0	0	0	+	++	++	++	*)	+	++	+
Food	+	0	0	0	0	0	0	++	++	++	*)	+	++	0
Hospital	0	0	0	0	0	0	0	++	++	++	*)	+	++	0

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

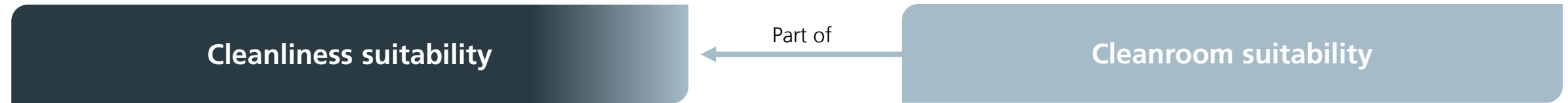
# Air cleanliness classes of cleanrooms and dry cleanrooms

## Overview of selected regulations

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 m <sup>3</sup>	per cbf	per m <sup>3</sup>	per cbf	per m <sup>3</sup>	per cbf	per m <sup>3</sup>	per cbf	per m <sup>3</sup>	per cbf	per m <sup>3</sup>	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		
										3.520	100				
	B										3.520	100			
		1.000	6			26.500	750	10.600	300	3.530	100				
				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			2.930	83
										352.000	9.972			2.930	83
										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			29.300	830
										3.520.000	99.716			29.300	830
										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 & cleanroom suitability

Definitions for atmospheric cleanroom conditions (ISO 14644-14, VDI 2083 series)



- **Cleanliness suitability** of systems/components includes all criteria relevant to a process in the cleanroom
- Criteria for cleanliness suitability include:
  - Particle release
  - Chemical resistance
  - Biological resistance
  - Antibacterial activity
  - Outgassing behavior
  - Cleanability
  - ESD behavior
  - Hygienic design/GMP conformity)
- **Cleanroom suitability** of systems/components describes the emission behavior of particles under cleanroom conditions and is one of the most important criteria in clean and hygienic areas
- The main cause of particle emission is tribological stress

# Dry room suitability & dry-cleanroom suitability

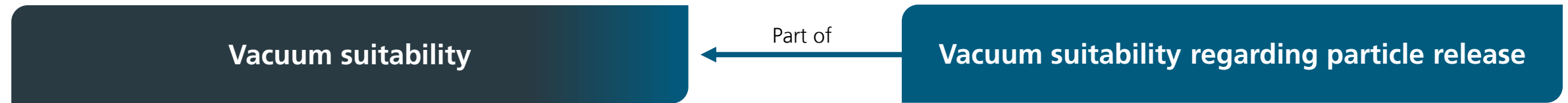
Definitions for dry and dry-cleanroom conditions (VDI-EE 2083 Part 4.3)



- **Dry room** suitability of systems/components includes all criteria relevant to a process in the dry room
- Criteria for dry room suitability include:
  - Mechanical strength
  - Shrinkage behavior
  - Corrosion resistance
  - Moisture absorption
  - Diffusion tightness
  - Chemical resistance
  - Particle release behavior (dry cleanroom suitability)
  - Electrostatic charge-discharge behavior
  - Aging behavior (due to dryness)
- **Dry cleanroom suitability** of systems/components describes the emission behavior of particles under dry cleanroom conditions and is one of the most important criteria in clean and dry areas
- The main cause of particle emission is tribological stress

# Vacuum suitability & vacuum suitability with particle release

## Definitions for vacuum conditions




- **Vacuum suitability** of systems/components includes all criteria relevant to a vacuum process
- Criteria for vacuum suitability according to Jousten (Handbook of Vacuum Technology) include:
  - Mechanical strength
  - Corrosion resistance
  - Gas tightness
  - Intrinsic vapor pressure
  - Content of foreign gases
  - Degassability
  - Melting and boiling temperature
  - Surface cleanliness
  - Expansion behavior
  - Thermal shock resistance
  - Chemical resistance
  - Outgassing behavior
  - Added to Jousten:  
Vacuum suitability regarding particle release
- **Vacuum suitability (particle release)** of systems/components describes the emission behavior of particles under vacuum conditions is one of the most important criteria in vacuum processes (Buerger 2017)
- The main cause of particle emission is tribological stress

# Fraunhofer test logo TESTED DEVICE®

For various test environments at Fraunhofer IPA

## Cleanroom (atmospheric)



**Fraunhofer**  
**TESTED®  
DEVICE**  
Company  
Product name  
Report No. CO 2510-3000


gültig bis: 17. November 2030

Cleanroom (atmospheric)



Class 1 clean room (ISO 14644-1) with relative humidity 45 %

## Dry-Cleanroom



**Fraunhofer**  
**TESTED®  
DEVICE**  
Company  
Product name  
Report No. CO 2510-3000

gültig bis: 17. November 2030

Dry-Cleanroom



Class 1 dry cleanroom (ISO 14644-1) with relative humidity < 1%

## Vacuum



**Fraunhofer**  
**TESTED®  
DEVICE**  
Company  
Product name  
Report No. CO 2510-3000

gültig bis: 17. November 2030

Vacuum



Vacuum chamber (vacuum pressure adjustable)  
Environment Class 1 cleanroom (ISO 14644-1)

# Database TESTED DEVICE®/CSM®

## Overview



The screenshot shows the website header with the Fraunhofer IPA logo, navigation links for Home, Manufacturer, and Tested Device®/CSM®, and a Login button with a US flag. The main content area features a background image of a KUKA robotic arm and a person in a cleanroom. The central text reads: "Certifying plants, equipment and materials for use in cleanrooms". Above this text are the logos for Fraunhofer IPA TESTED DEVICE, CSM, and Cleanroom® Suitable Materials. Below the main text is the subtitle "Fraunhofer Tested Device® / CSM® database".

# Business unit Testing & Certification



Fraunhofer-Institut für Produktions-  
technik und Automatisierung IPA

- **Head of business unit**
  - *Dr.-Ing. Frank Bürger*  
phone: +49 711 970-1148
- **Business segment manager**
  - *Dipl.-Ing. (FH) Marion Schweizer*  
phone: +49 711 970-1509
- **Staff members of business unit**
  - Dipl.-Ing. Eileen Junghans
  - M. Sc. Jasmin Bürger

[qualification@ipa.fraunhofer.de](mailto:qualification@ipa.fraunhofer.de)

▶ <https://www.tested-device.de/en/>

**We produce the future**

Sustainable. Personalized. Smart.