



Company  
Report No. CO 2510-3000

# Cleanroom<sup>®</sup> Suitable Materials

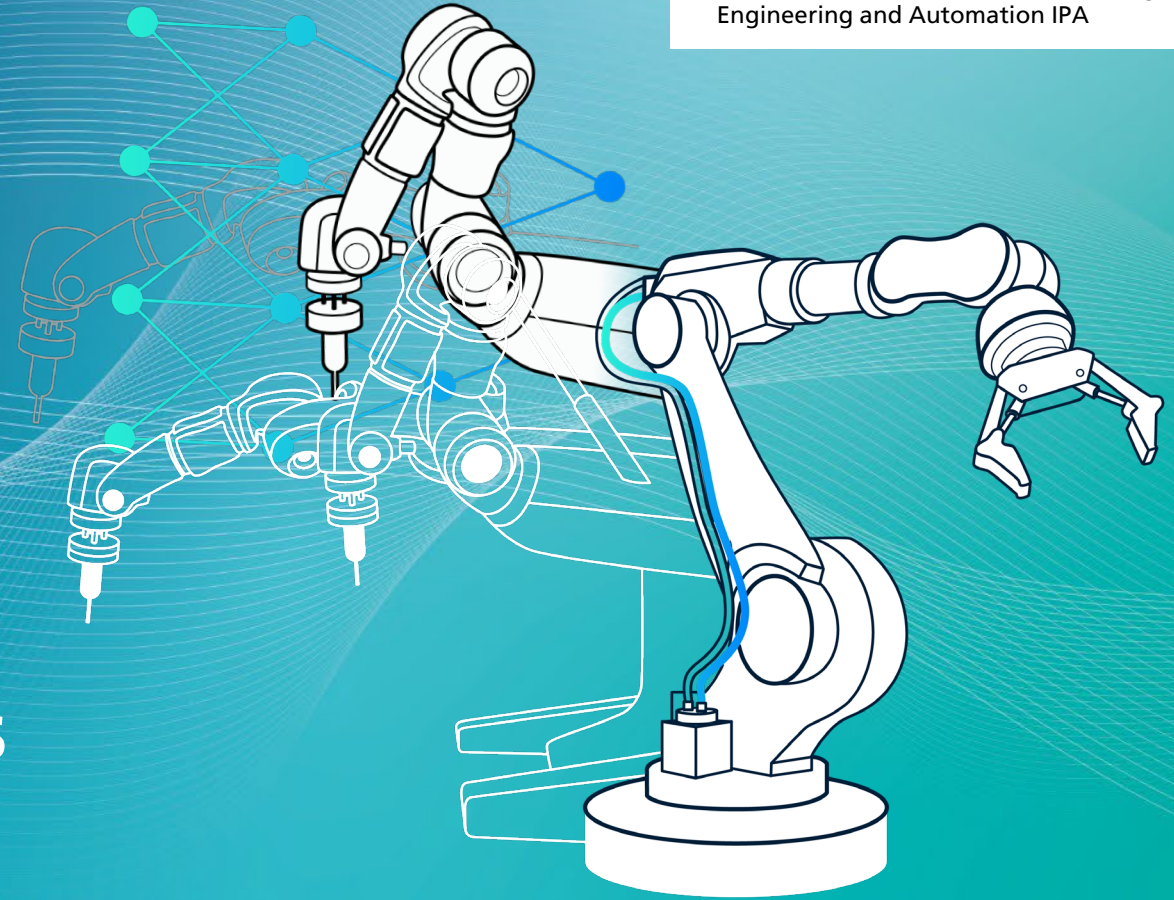
Product name  
Particle (vs. PA6 Nylon): ISO X



Fraunhofer Institute for Manufacturing  
Engineering and Automation IPA

# CSM<sup>®</sup> Certification Cleanroom Suitable Materials

Develop, ensure and communicate quality



# Business unit Testing & Certification, business segment Cleanliness

Determination of the cleanliness suitability of materials



*„To determine the suitability of materials for production areas with cleanliness requirements (ISO 14644 and VDI 2083 series), Fraunhofer IPA carries out various tests in accordance with national and international regulations.“*

# Industry products and categories – TESTED DEVICE®/CSM® 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		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>Production Environment</b>
	Lubricants / sealants / adhesives	Production lines	
	Consumables	Chairs	
	Liquids	<b>Working Place and Operator</b>	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
Semiconductor	++	0	++	++	+	+	++	+	+	+	0	0
Electronic	++	0	0	+	+	+	++	0	0	0	0	0
Display (e.g. mobile phone)	++	0	++	+	0	0	++	0	0	0	0	0
Battery	+	++	0	0	0	0	++	0	0	0	0	0
Microsystems	++	0	0	+	0	0	++	+	+	+	0	0
Optic	++	+	++	++	+	+	+	+	+	+	0	0
Photovoltaic	+	0	+	+	0	0	+	0	0	0	0	0
Aerospace	++	++	++	++	+	+	++	+	+	+	+	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	++	++	++	*)	+
Hospital	0	0	0	0	0	0	0	++	++	++	*)	+

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

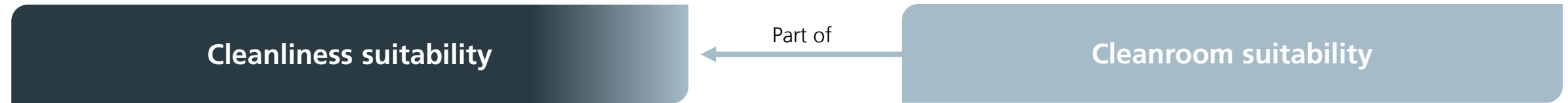
# Air cleanliness classes of cleanrooms and dry cleanrooms

## 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

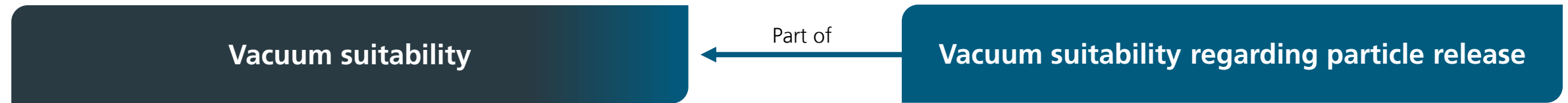
Definitions for dry and dry-cleanroom conditions (VDI-EE 2083 Part 4.3)



- **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 label CSM<sup>®</sup> – Cleanroom Suitable Materials

For various test environments at Fraunhofer IPA

## Cleanroom (atmospheric)



**Cleanroom<sup>®</sup>  
Suitable  
Materials**

Company  
Report No. CO 2510-3000  
Cleanroom (atmospheric)

Product name  
vs. reel PA6: ISO X  
Particle Emission (flooring)



### Material pairings :

- Ball/disc
- Reel/disc

## Dry-Cleanroom



**Cleanroom<sup>®</sup>  
Suitable  
Materials**

Company  
Report No. CO 2510-3000  
Dry-Cleanroom

Product name  
vs. reel PA6: ISO X  
Particle Emission (flooring)



### Material pairings :

- Ball/disc
- Reel/disc

## Vacuum



**Cleanroom<sup>®</sup>  
Suitable  
Materials**

Company  
Report No. CO 2510-3000  
Vacuum

Product name  
vs. reel PA6: ISO X  
Particle Emission



### Material pairings :

- Ball/disc
- Reel/disc
- Gripping elements
- Ball bearing

# 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 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 Institute for Manufacturing  
Engineering and Automation 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/>

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