Fraunhofer Institute for Manufacturing Engineering and Automation IPA

Director
Prof. Dr.-Ing. Thomas Bauernhansl

Nobelstraße 12
70569 Stuttgart

Phone +49 711 970-00
Fax +49 711 970-1399

Measurement report

Cleanliness suitability and cleanroom suitability tests at Fraunhofer IPA

Customer: Thomas Engineering Co., Ltd.
#397, Sindaeseokseong-ro, Bugi-myeon,
Cheongwon-gu
28133 Cheongju-si, Chungcheongbuk-do
Republic of Korea

Project Manager: Dr.-Ing. Frank Bürger

Project Assistants: CTA Andrew Schönhaar
Dipl.-Ing. (FH) Marion Schweizer

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Fraunhofer IPA

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1 Introduction and objectives

Thomas Engineering Co., Ltd. is a manufacturer of cable systems and corresponding accessories. These products are manufactured under high quality standards and successfully implemented in a wide range of industries.

To secure the market position of the Thomas Engineering Co., Ltd. in the sector of "clean" industries, the company wishes to enlarge the application of its products to clean manufacturing areas. To do this, it is essential to understand the contamination behavior of their products. Therefore, PODFLEX 4 x 0.75 mm^2 need to be examined and assessed for cleanliness- and cleanroom suitability.

2 Overview of the measurements

Tests were conducted on **PODFLEX 4 x 0.75 mm²** which is henceforth simply called test piece **TP01** in the report.

The following table shows the exact breakdown of the test piece:

TP01	
Description of test piece	PODFLEX 4 x 0.75 mm²
Company name	Thomas Engineering Co., Ltd.
Category **Subcategory**	Energy Supply Cable Systems
Serial number	3CA00118
Batch number	H-G26
Color	Black
Manufacturing date	7/26/2018

Figure 1 Test piece data TP01

3 Overview of results

TP01: **Particle emission** (ISO 14644-1, -14)	
Test parameter(s)	**Air Cleanlines Class**
v_1 = 0.5 m/s; a_1 = 1.0 m/s^2	1
v_2 = 1.0 m/s; a_2 = 2.0 m/s^2	1
v_3 = 2.0 m/s; a_3 = 4.0 m/s^2	1
Overall result	**1**

Figure 2 Overview of results

4 Airborne particle emission tests

4.1 General information

A major criterion in clean and hygienic areas in industry and research is the concentration of airborne particles. Besides the quantity of particles per unit of volume of air, the size distribution of the particles is also critical when it comes to fulfilling cleanliness requirements.

Cleanliness requirements are set against the release of particles from the operating utilities used in clean or hygienic areas. The cause of particle emissions from operating utilities is generally tribological stress, which leads to wear and the generation and release of particles.

To determine the release of particles from operating utilities, particle emission measurements can be conducted in a test cleanroom with a low-turbulence displacement airflow following the procedure laid down in ISO 14644-14. The results enable the suitability of operating utilities to be determined for use in discrete air cleanliness classes according to ISO 14644-1. The VDI 2083 series uses the term **cleanroom suitability** to describe the suitability of operating utilities for discrete air cleanliness classes. Cleanroom suitability is one aspect of **cleanliness suitability**, which also includes all other cleanliness criteria relevant to a process. Apart from the release of particles, other cleanliness suitability criteria are, for example, chemical resistance, biological resistance, microbicidity and outgassing from materials, as well as the cleanability and hygienic design of components or equipment.

In the case of operating utilities such as manufacturing equipment, particle emission measurements serve not only to determine the influence of these systems on the environment (protection of the cleanroom) but also on the interior of the equipment itself (protection of the product).

By conducting localized particle emission measurements with optical particle counters in a test cleanroom with a low-turbulence displacement airflow, the cause of high particle emissions can be derived from the results obtained from the various measuring points.

4.2 Cleanroom environment

All tests are carried out in the Fraunhofer IPA competence center for ultraclean technology and micromanufacturing. Measurements are performed in a cleanroom fulfilling Class 1 specifications (in accordance with ISO 14644-1). A vertical low-turbulence displacement airflow prevails in the cleanroom. Air is introduced via the ceiling and extracted via a raised floor. The velocity of the flow of first air (filtered air introduced into the cleanroom) is 0.45 m/s. Environmental conditions in the cleanroom are kept constant with a room temperature of 22 °C ± 0.5 °C and a relative humidity of 45 % ± 5 %.

According to ISO 14644-1, Cleanroom Class 1 means that only ten particles the size of 0.1 µm may be found a reference volume of one cubic meter. In practical operation, even fewer particles are found in this cleanroom class.

4.3 Test set-up and parameters

Test set-up
Thomas Engineering Co., Ltd. supplied Fraunhofer IPA with the test piece. The test piece was suitable for continuous, maintenance-free operation

On delivery, the test piece was introduced into the cleanroom at the Fraunhofer IPA in Stuttgart. It was then assembled and put into operation (complete with all the functional components required for its assembly and operation) by the Fraunhofer IPA.

Pre-conditioning of the test piece
The test piece was first operated in the reference cleanroom with a typical average load for a period of 24 hours while exposed to a flow of clean first air. In this way, the raised quantity of particles emitted during the running-in phase, which is not representative as far as later operation is concerned, is not included in the assessment.

Test parameters
To determine particle emissions from the test piece, it was operated using the parameters specified below.

The operating parameters selected for the test piece were arranged with the customer before the start of the project:

- Bending radius: ..... 75 mm
- Stroke length: ..... 820 mm
- Parameter Set 1
  - Velocity: ..... v_1 = 0.5 m/s
  - Acceleration: ..... a_1 = 1.0 m/s²
- Parameter Set 2
  - Velocity: ..... v_2 = 1.0 m/s
  - Acceleration: ..... a_2 = 2.0 m/s²
- Parameter Set 3
  - Velocity: ..... v_3 = 2.0 m/s
  - Acceleration: ..... a_3 = 4.0 m/s²

Overview of the test set-up and test piece TP01

Figure 3 Overview of the test set-up and test piece TP01

4.4 Measuring equipment

In the tests to determine particle emissions, the following type of laser particle measuring device was used.

Type LasAir II 110 / LasAir III 110 from PMS with the measuring ranges of ≥ 0.1 µm, ≥ 0.2 µm, ≥ 0.3 µm, ≥ 0.5 µm, ≥ 1.0 µm and ≥ 5.0 µm

Optical particle counters function according to the principle of scattered light. Via a sampling probe, a defined volume of air of 1 cubic foot (1 cft = 28.3 liters) is sucked in every minute and guided into a measuring chamber via a tube connected to it. The air sucked in is illuminated by a light source - in modern devices either a laser or laser diode. As soon as a particle carried by the airflow is struck by the beam of light, light is scattered and recorded by photo-detectors.

The number of impulses recorded corresponds with the number of particles present in the volume of air. The amplitude of the impulses indicates the particle size.

4.5 Localization tests

To select the measuring points for the subsequent qualification tests, separate localization tests were performed for each set of parameters.

Critical contamination sites (these are generally areas subjected to tribological stress, such as bearings slits) were systematically investigated for particle emissions, taking into consideration the motion sequences planned. The surface of the test piece was also visually assessed. By comparing the values obtained, sites could be identified where especially high levels of particulate emission were generated during motion sequences. A particle measuring probe was carefully positioned at these sites to detect the maximum number of particles being emitted from the test object.

4.6 Qualification measurements

4.6.1 Procedure

The qualification tests were performed according to ISO 14644-14.

Measuring probes were placed at each of the critical sites identified (= measuring points). At each measuring point, particle emission measurements were recorded with measuring intervals of 1/min over a period of 100 minutes. To better compare results, up to 3 particle counters were used in parallel at up to 3 different measuring points for each test series to record particle emission values.

The measurement volume is sucked in at a rate of 1 cft/min. Particle measurements are shown cumulatively for each particle size channel, i.e. the figure shown for a particle size channel refers to all particles equal to or larger than the particle size channel stated (≥ 0.1 µm, ≥ 0.2 µm, ≥ 0.3 µm, ≥ 0.5 µm, ≥ 1.0 µm or ≥ 5.0 µm).

The selected time of 100 minutes ensures adequate statistical certainty of the test results and safeguards against faulty measurements. Each measurement value contains information about the particle size, the quantity of particles generated and the site where the particles were emitted.

The results were analyzed statistically conform to the procedure described in the guideline ISO 14644-14, thus enabling the suitability of the operating utility for use in cleanrooms classified according to ISO 14644-1 to be determined.

4.6.2 Test piece TP01: description of the measuring points MP01 to MP03

The following photographs show the exact points selected to measure airborne particles emitted from the test piece.

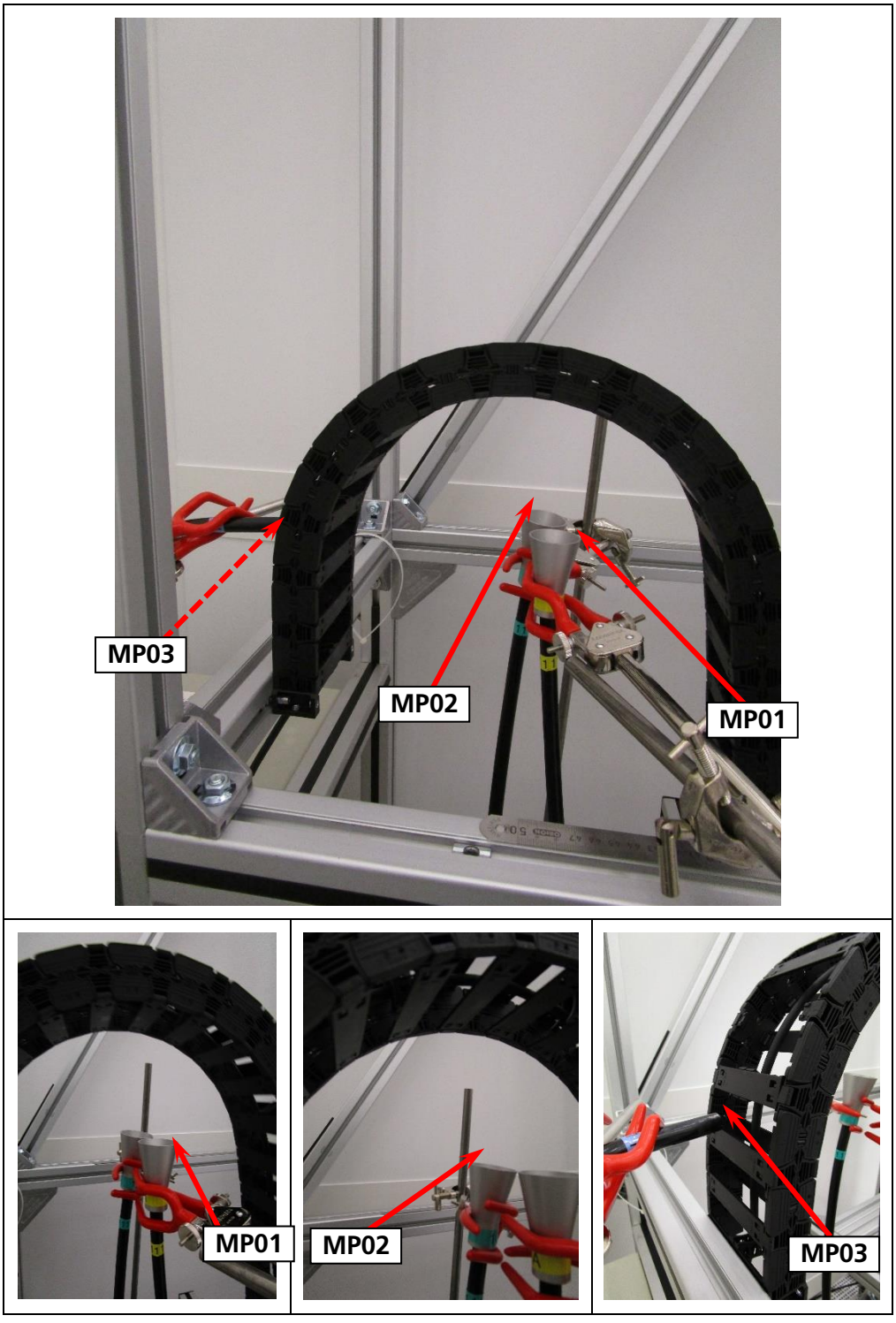

Figure 4 Measuring points MP01 to MP03 selected to measure airborne particle emissions from TP01

4.6.3 Course of particle emissions over time for TP01

The following diagrams show the course of particle emissions at each of the measuring points, as well as for the stated particle size channels, over the total testing time required by the qualification test. The measuring interval of 1 min was the same for all tests. This equates to a test volume of cubic foot (cft).

Occurrence of contamination over time:

4.6.3.1 Parameter Set 1

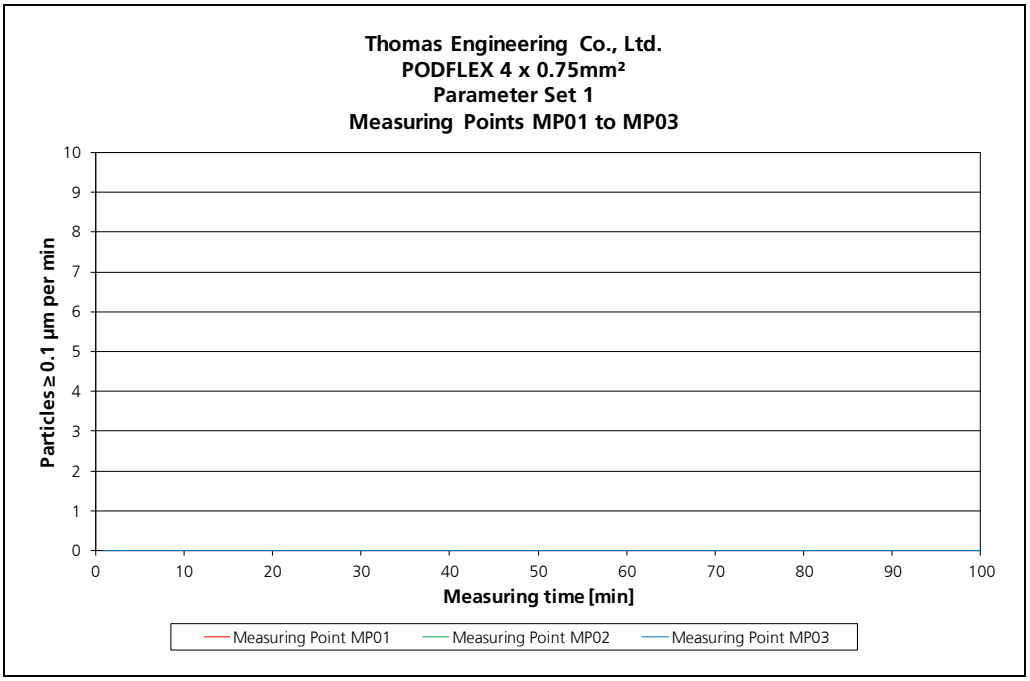

Figure 5 Course of the emission of airborne particles
≥ 0.1 µm over time from the test piece at measuring points MP01 to MP03 over the period of 100 minutes

4.6.3.2 Parameter Set 2

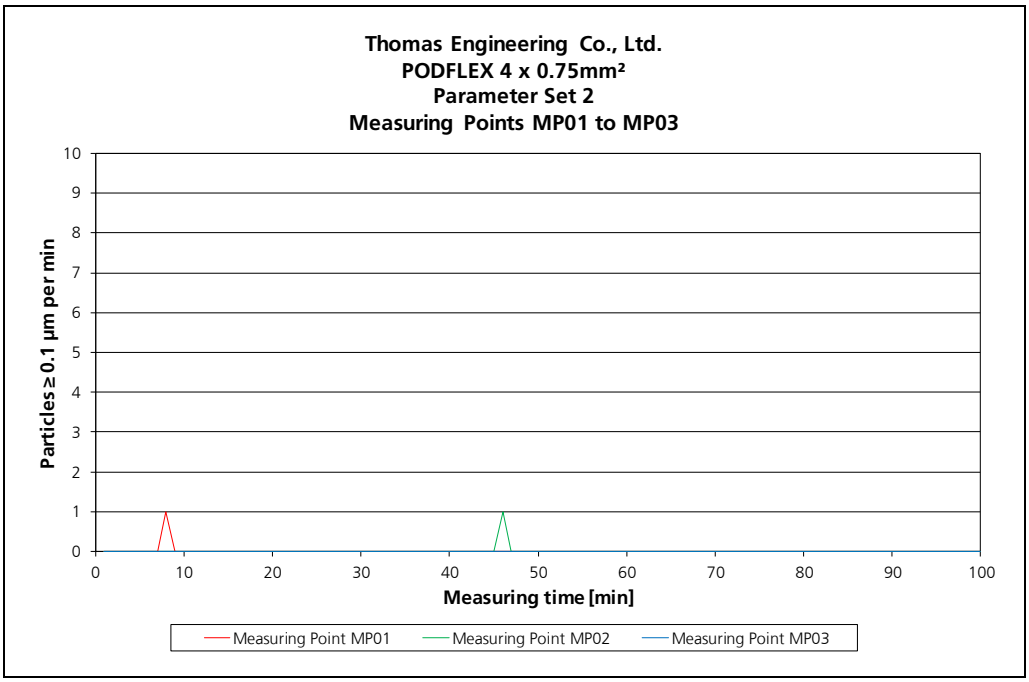

Figure 6 Course of the emission of airborne particles ≥ 0.1 µm over time from the test piece at measuring points MP01 to MP03 over the period of 100 minutes

4.6.3.3 Parameter Set 3

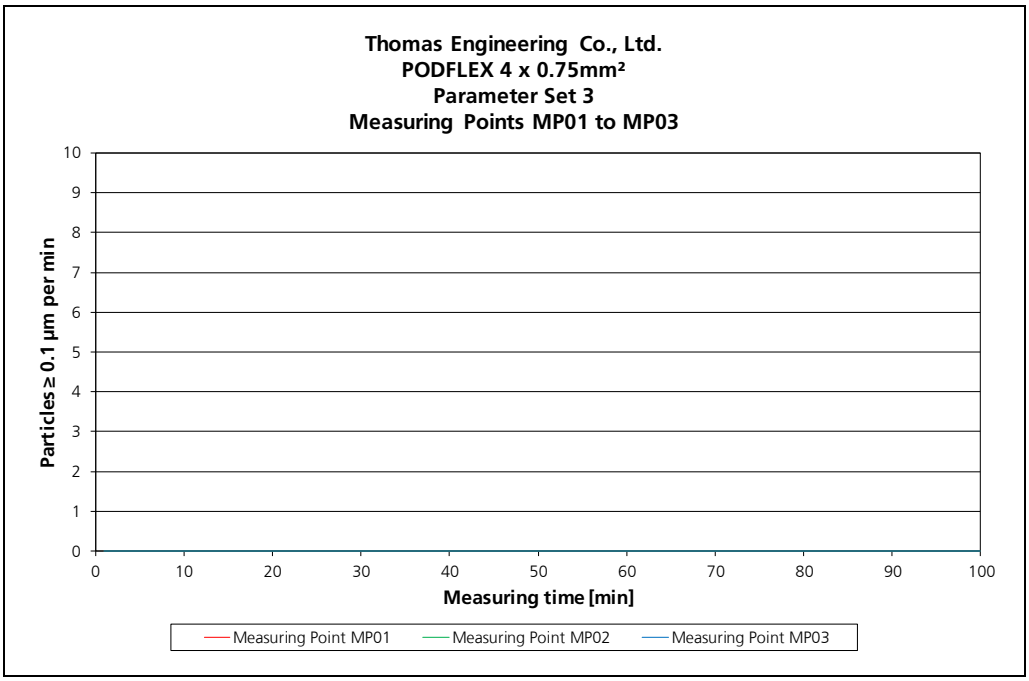

Figure 7 Course of the emission of airborne particles ≥ 0.1 µm over time from the test piece at measuring point MP01 to MP03 over the period of 100 minutes

4.7 Classification

The aim of the tests was to ascertain to what extent the test piece may be operated in clean environments. For this, based on the procedure described in the guideline "Assessment of suitability for use of equipment by airborne particle concentration ISO 14644-14", the empirically-calculated measurement values were analyzed statistically and assessed according to the class limits stated in ISO 14644-1.

4.7.1 Statistical verification of the test results

International standards defining air cleanliness, such as ISO 14644-1, state limit values for the air cleanliness classes that are defined in the respective norm. These limit values are set for a specific number of particle size channels (e.g. ≥ 0.1 µm, ≥ 0.2 µm, ≥ 0.3 µm, ≥ 0.5 µm, ≥ 1.0 µm and ≥ 5.0 µm). When comparing empirically-derived values (e.g. from a qualification test) with such limit values, a certain degree of certainty is required by which the limit value may not be exceeded.

When classifying operating utilities, the standard deviation and mean values are calculated from the measurement values obtained. ISO 14644-14 describes a method which correlates these values with the limit values stated in ISO 14644-1. If a test piece is declared suitable for different classes, the assessment of the test piece is based on the highest class (worst-case assumption).

4.7.2 Mean and maximum particle emission values and classification for TP01

The following tables show the respective maximum values and arithmetical mean values of particle emissions recorded at the corresponding measuring points (MP) over the total testing time of 100 minutes. The applicable air cleanliness class according to ISO 14644-1 for each measuring point is highlighted.

4.7.2.1 Parameter Set 1

Thomas Engineering Co., Ltd. PODFLEX 4 x 0.75mm² Parameter Set 1 Measuring Points MP01 to MP03				
Statistical parameters		Measuring Point		
		MP01	MP02	MP03
Mean value for the detection size [particles / cft]	0.1 µm	0.0	0.0	0.0
	0.2 µm	0.0	0.0	0.0
	0.3 µm	0.0	0.0	0.0
	0.5 µm	0.0	0.0	0.0
	1.0 µm	0.0	0.0	0.0
	5.0 µm	0.0	0.0	0.0
Standard deviation for the detection size [particles / cft]	0.1 µm	0.0	0.0	0.0
	0.2 µm	0.0	0.0	0.0
	0.3 µm	0.0	0.0	0.0
	0.5 µm	0.0	0.0	0.0
	1.0 µm	0.0	0.0	0.0
	5.0 µm	0.0	0.0	0.0
Air Cleanliness Class [ISO 14644-1]		**1**	**1**	**1**
Maximum value for the detection size [particles / cft]	0.1 µm	0	0	0
	0.2 µm	0	0	0
	0.3 µm	0	0	0
	0.5 µm	0	0	0
	1.0 µm	0	0	0
	5.0 µm	0	0	0
Minimum value for the detection size [particles / cft]	0.1 µm	0	0	0
	0.2 µm	0	0	0
	0.3 µm	0	0	0
	0.5 µm	0	0	0
	1.0 µm	0	0	0
	5.0 µm	0	0	0

Figure 8 Statistical characteristics of the measuring points MP01 to MP03

From the respective calculations for the detection sizes ≥ 0.1 µm, ≥ 0.2 µm, ≥ 0.3 µm, ≥ 0.5 µm, ≥ 1.0 µm and ≥ 5.0 µm, it can be derived that the test piece is suitable for use in **ISO Class 1** cleanrooms according to ISO 14644-1.

4.7.2.2 Parameter Set 2

Thomas Engineering Co., Ltd. PODFLEX 4 x 0.75mm² Parameter Set 2 Measuring Points MP01 to MP03				
Statistical parameters		**Measuring Point**		
		MP01	MP02	MP03
Mean value for the detection size [particles / cft]	0.1 µm	0.0	0.0	0.0
	0.2 µm	0.0	0.0	0.0
	0.3 µm	0.0	0.0	0.0
	0.5 µm	0.0	0.0	0.0
	1.0 µm	0.0	0.0	0.0
	5.0 µm	0.0	0.0	0.0
Standard deviation for the detection size [particles / cft]	0.1 µm	0.1	0.1	0.0
	0.2 µm	0.0	0.0	0.0
	0.3 µm	0.0	0.0	0.0
	0.5 µm	0.0	0.0	0.0
	1.0 µm	0.0	0.0	0.0
	5.0 µm	0.0	0.0	0.0
Air Cleanliness Class [ISO 14644-1]		**1**	**1**	**1**
Maximum value for the detection size [particles / cft]	0.1 µm	1	1	0
	0.2 µm	0	0	0
	0.3 µm	0	0	0
	0.5 µm	0	0	0
	1.0 µm	0	0	0
	5.0 µm	0	0	0
Minimum value for the detection size [particles / cft]	0.1 µm	0	0	0
	0.2 µm	0	0	0
	0.3 µm	0	0	0
	0.5 µm	0	0	0
	1.0 µm	0	0	0
	5.0 µm	0	0	0

Figure 9 Statistical characteristics of the measuring points MP01 to MP03

From the respective calculations for the detection sizes ≥ 0.1 µm, ≥ 0.2 µm, ≥ 0.3 µm, ≥ 0.5 µm, ≥ 1.0 µm and ≥ 5.0 µm, it can be derived that the test piece is suitable for use in **ISO Class 1** cleanrooms according to ISO 14644-1.

4.7.2.3 Parameter Set 3

Thomas Engineering Co., Ltd. PODFLEX 4 x 0.75mm² Parameter Set 3 Measuring Points MP01 to MP03				
Statistical parameters		**Measuring Point**		
		MP01	MP02	MP03
Mean value for the detection size [particles / cft]	0.1 µm	0.0	0.0	0.0
	0.2 µm	0.0	0.0	0.0
	0.3 µm	0.0	0.0	0.0
	0.5 µm	0.0	0.0	0.0
	1.0 µm	0.0	0.0	0.0
	5.0 µm	0.0	0.0	0.0
Standard deviation for the detection size [particles / cft]	0.1 µm	0.0	0.0	0.0
	0.2 µm	0.0	0.0	0.0
	0.3 µm	0.0	0.0	0.0
	0.5 µm	0.0	0.0	0.0
	1.0 µm	0.0	0.0	0.0
	5.0 µm	0.0	0.0	0.0
Air Cleanliness Class [ISO 14644-1]		**1**	**1**	**1**
Maximum value for the detection size [particles / cft]	0.1 µm	0	0	0
	0.2 µm	0	0	0
	0.3 µm	0	0	0
	0.5 µm	0	0	0
	1.0 µm	0	0	0
	5.0 µm	0	0	0
Minimum value for the detection size [particles / cft]	0.1 µm	0	0	0
	0.2 µm	0	0	0
	0.3 µm	0	0	0
	0.5 µm	0	0	0
	1.0 µm	0	0	0
	5.0 µm	0	0	0

Figure 10 Statistical characteristics of the measuring points MP01 to MP03

From the respective calculations for the detection sizes ≥ 0.1 µm, ≥ 0.2 µm, ≥ 0.3 µm, ≥ 0.5 µm, ≥ 1.0 µm and ≥ 5.0 µm, it can be derived that the test piece is suitable for use in **ISO Class 1** cleanrooms according to ISO 14644-1.

4.8 Summary of the classification results

The following table gives an overview of the classification of the various measuring points MP01 to MP03:

PODFLEX 4 x 0.75 mm² manufactured by Thomas Engineering Co., Ltd.			
Parameter Set 1			
Measuring Point	MP01	MP02	MP03
Air Cleanliness Class (acc. to ISO 14644-1)	1	1	1
Parameter Set 2			
Measuring Point	MP01	MP02	MP03
Air Cleanliness Class (acc. to ISO 14644-1)	1	1	1
Parameter Set 3			
Measuring Point	MP01	MP02	MP03
Air Cleanliness Class (acc. to ISO 14644-1)	1	1	1

Figure 11 Overall classification of the cable PODFLEX 4 x 0.75 mm²

From the calculations of the probability of exceeding limiting values for the detection sizes ≥ 0.1 µm, ≥ 0.2 µm, ≥ 0.3 µm, ≥ 0.5 µm, ≥ 1.0 µm and ≥ 5.0 µm, it can be derived that the cable **PODFLEX 4 x 0.75 mm²** manufactured by **Thomas Engineering Co., Ltd.** is suitable for use in cleanrooms fulfilling the specifications of **ISO Class 1** in accordance with ISO 14644-1 when operated with the specified parameters.

4.9 Annex: comparison of different classifications of airborne particulate contamination

In the following table, the limit values defining air cleanliness classes according to the international standard **ISO 14644-1** are compared with the limit values stated in **EG GMP Guideline** Volume 4 Annex 1 and in the American norm **US Federal Standard 209E** (retracted). The comparison concerns the particle size channels stated explicitly in ISO 14644-1; limit values are stated for the reference volumes of 1 m³ and 1 cft (1 cubic foot = 0.0283 m³).

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						
			3	1,000	30	237	7	102	3	35	1				
		1		1,240	35	265	8	106	3	35	1				
			4	10,000	300	2,370	67	1,020	29	352	9,9	83	2		
		10		12,000	340	2,650	75	1,060	29	353	10				
			5	100,000	2,833	23,700	671	10,200	289	3,520	100	832	24		
	A									3,520	100			20	0,6
A										3,520	100			20	0,6
	B									3,520	100			29	0,8
		100				26,500	750	10,600	300	3,530	100				
			6	1,000,000	28,329	237,000	6,710	102,000	2,890	35,200	997	8,320	235	293	8
		1,000								35,300	1,000			247	7
			7							352,000	9,972	83,200	2,357	2,930	83
B										352,000	9,972			2,900	82
	C									352,000	9,972			2,900	82
		10,000								353,000	10,000			2,470	70
			8							3,520,000	99,716	832,000	23,569	29,300	830
C										3,520,000	99,716			29,000	821
	D									3,520,000	99,716			29,000	821
		100,000								3,530,000	100,000			24,700	700
			9							35,200,000	997,167	8,320,000	235,694	293,000	8,300

Figure 12 Overview of limit values for airborne particles per m³ or cft for the standards ISO 14644-1, EU GMP Guideline Volume 4, Annex 1 and US Federal Standard 209E (retracted)

Although limit values are stated for tests on **biotic** airborne particles in EU GMP Guideline Volume 4, Annex 1, this does not form part of the qualification tests conducted at Fraunhofer IPA. Since all manufacturing environments have their own individual germ spectrum, these tests cannot be conducted in a reference laboratory and therefore need to be performed in the respective manufacturing environment. The individual germ spectrum and magnitude of microbial loads are decisively influenced by the production processes, the environment and operating staff in the relevant production areas.