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# Clean Room Die Cutting

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## Die Cutting: Clean Practices and Cleanroom Options

Cleanroom die cutting combines the speed and precision of manufacturing with a controlled environment with low levels of pollutants. Cleanrooms reduce particulate contamination and control environmental parameters such as temperature, humidity, static, and pressure. Applications include laboratory diagnostics, medical devices, biomedical technology, filtration, electronics, and scientific research.

In this white paper from Interstate Specialty Products (ISP), you'll learn about cleanroom requirements, classifications, and the role of quality management systems (QMS). You'll also examine the equipment, dies, and materials that are often used. Importantly, you'll discover the types of complex components that cleanroom die cutting can create for you. ISP operates a Class 100,000 (M6.5, ISO Class 8) cleanroom and maintains a QMS that is ISO 9001:2015 and ISO 13485:2016 certified.

## 1. Cleanroom Requirements, Classifications, and Quality

In a cleanroom, the die cutting equipment must not contaminate the environment. The machinery must not contaminate the material either. Cleanroom operations need to maintain an air filtration system, equip personnel with garments that won't release substances from the wearer's body, and provide operators with proper training and instruction. Environmental monitoring and regular cleaning are essential. Cleanroom die cutters must also meet the requirements for a specific cleanroom standard.

Cleanrooms are classified by the number and size of particles that are permitted per volume of air. Federal Standard 209E (FED-STD-209E) limits the number of particles with sizes equal to and greater (≥) than 0.5 micrometers (μm) in one cubic foot ($ft^3$) of air. Cleanroom classifications also account for other sizes of particles, but Class 100,000 cleanrooms are so named because they permit a maximum of 100,000 particles that are ≥ 0.5 μm in 1 $ft^3$ of air.

FED-STD-209E was retired in 2001, but its classifications are still widely used today. For metric units, Class 100,000 cleanrooms are designated as M6.5. Under the ISO 14644-1 standard, ISO Class 8 is equivalent to Class 100,000. The following table compares cleanroom classifications and the concentration of ≥ 0.5 μm particles per $ft^3$.

| FED-STD-209E Class | Metric Designation | ISO Equivalent | Maximum particles @ ≥ 0.5 µm |
|---|---|---|---|
| 1 | M1.5 | ISO 3 | 1 |
| 10 | M2.5 | ISO 4 | 10 |
| 100 | M3.5 | ISO 5 | 100 |
| 1000 | M4.5 | ISO 6 | 1000 |
| 10,000 | M5.5 | ISO 7 | 10,000 |
| 100,000 | M.65 | ISO 8 | 100,000 |

ISO standards for quality management systems are not specific to cleanrooms, but some customers may need a cleanroom die cutter with an ISO 9001-certified QMS. Today, ISO 9001:2015 is replacing ISO 9001:2008 with updated standards to better assess risk management. ISO 13485 is based on the ISO 9001 standard but contains additional requirements for medical device manufacturers.

## 2. Cleanroom Die Cutting Equipment

In a cleanroom, die cutting equipment is free from exposed, moving parts that could introduce contamination into the air or onto surrounding surfaces. This equipment is easy-to-clean and supports the use of cleaning agents. Press enclosures are usually water-resistant. Instead of knobs, touchpads are used. Press features include smooth surfaces, rounded areas, and the absence of areas where contaminants can easily settle.

Cleanroom die cutting is also designed to avoid contamination from machine oils or fluids. With pneumatic pumps, the air supply is generated outside the room with lines running in and out. If hydraulics are used instead, any fumes are removed. Because the housings that hide moving parts may obscure sightlines, some cleanroom die cutting equipment uses machine vision.

## 3. Cleanroom Die Cutting Materials

Cleanroom die cutting often uses FDA, ASTM, MIL-SPEC, or NSF approved materials. Examples include filter media, tapes, membranes, labels, and adhesives. Since clean rooms may be sensitive to material outgassing, die cutters may recommend elastomers such as platinum-cured silicones instead of peroxide-cured products. Platinum-cured silicones can also meet USP Class VI requirements for compounds made from ingredients with clear histories of biocompatibility.

High-purity materials for cleanroom die cutting include specialized grades of PTFE, a synthetic fluoropolymer. The advantages of high-purity PTFE are numerous, and include thermal stability, flame and chemical resistance, cryogenic properties, and a low dielectric constant. Like platinum-cured silicones, high-purity PTFE products are supplied in sheets or continuous rolls for fast, precise, and cost-effective die cutting

## 4. Clean Practice Die Cut Products

Clean practice die cutting is ideal for vents and chromatography frits. Die cut vents are used with catheters, drainage bags, sterilization, suction canisters, and medical and surgical instruments. Die cut chromatography frits are used in laboratory-scale liquid and gas filtration. Often, liquid chromatography (LC) or gas chromatography (GC) is used with mass spectrometry (MS). Die cut chromatography frits are also used with solid phase extraction (SPE) columns.

Other die cut components may include custom wicks, membrane filters, and filter media. Die cut wicks are optimized for media capillarity and control both liquid volume capacity and transfer. Die cut membrane filters are used in protein detection, diagnostic cytology, gas sterilization, and high-performance liquid chromatography (HPLC). Die cut filter media are deployed in numerous life science, clinical, and microbiology applications.

Components that are often produced in clean practice manufacturing facilities include medical seals and gaskets, filters for medical equipment, microfluidic devices, and packaging for medical supplies. For these and other products, customers in the laboratory diagnostics, medical and biomedical technology, filtration, and electronic industries need a skilled die cutter. The right cleanroom classification and QMS certifications are important, but you also need a partner with vendor relationships and manufacturing expertise.

## 5. Cleanroom Die Cutting from Interstate

Interstate Specialty Products (ISP) maintains a Class 100,000 cleanroom and is both ISO 9001:2015 and ISO 13485:2016 certified. ISP sources USP Class VI silicones, high-purity PTFE, Porex® porous polymers, and materials that meet FDA, ASTM, MIL-SPEC, or NSF requirements. We also add value through services such as slitting, laminating, white room assembly, OEM packaging, and just-in-time delivery (JIT) delivery.

Customers who need cleanroom die cutting choose ISP for rapid prototyping, small-to-large production runs, miniature parts, and complex components. We can achieve tolerances as close as ± 0.005 and offer part sizes as large as 60” to 120”. Vents, chromatography frits, wicks, membrane filters, and filter media are just some of products we can die cut for you in our Class 100,000 cleanroom. Contact us to learn more.