



*Eagle's eye to Quality*

**BETTER SOLUTION**  
**FOR CLEANROOM CONSUMABLES**

[www.june4gmp.com](http://www.june4gmp.com) | [www.jeclin.co](http://www.jeclin.co)

# June Enterprises Pvt. Ltd.

Appreciated by customers across the nation for supplying, trading and wholesaling a broad array of high quality Pharmaceutical Hygiene & Cleanroom Products, June Enterprises started its operations in December 2013.

In a short span of time, the company expanded its breadth of operations to provide Cleanroom Products to the Indian pharmaceutical industry & neighboring countries.

The product range offered by June Enterprises includes:– Sterilization Monitoring & Validation Products, ATCC® Culture, Cleanroom Garments & Accessories, Cleanroom Supplies, Critical Cleaning Products, Products for Food & Facilities, Sterilization Packaging & Sealing Products, Products for Stores & Warehouses, USP Class Silicone Tubing among others.

In order to ensure high standards of quality, the offered range of cleanroom products is procured and sourced from trusted and reliable leaders in their respective product ranges, for example, Sterilization Products by Mesa Labs, Cleaning & Disinfectants by Contec® & ATCC® by Microbiologics.

The strength of unmatched quality of products is supported by documentation & trained workshop for regulatory requirements.

Backed by an efficient workforce, we have been able to cater to the needs of our valuable customers in the most efficient manner. With excellent competence in their area of operation, our employees work in close coordination with each other to manage inconveniences and unforeseen circumstances at the workplace.

With years of experience, expertise and a proven track-record of helping many companies with its Cleanroom Products & Sterilization needs, June Enterprises has established an enviable position in the PHARMA, FOOD & HOSPITAL segments.

ISO 9001-2015 Certified Company

## Sankalp

We aim to provide complete customer satisfaction through timely delivery of Highest Quality Product and Services with continual improvements in the Quality System based on customer feedback. All of our employees are contributing to these goals with the highest professionalism in conducting business.

*- Team June*

10 YEARS OF JOURNEY TOWARDS 100 SANKALP



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# Chemical Indicators

## Bowie Dick Type



BD Test Sheet (A4)

Air Removal Test Pack – Intended to evaluate the performance of the Air Removal (vacuum) system of pre-vacuum equipped steam sterilizers.

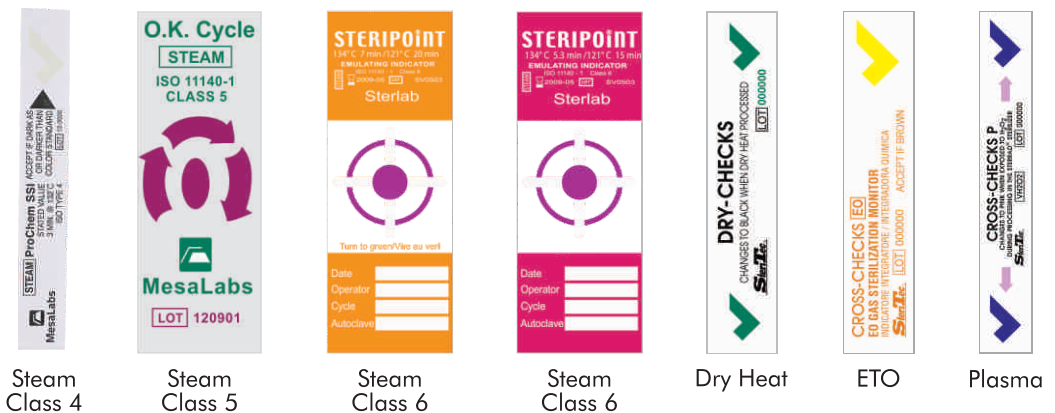
Available in different types as follows :

- 121°C - 8.3 min
- 121°C – 10 Min
- 121°C – 11 Min
- Reusable/Disposable BD Test Pack
- B D Test Paper for towel/linen pack.
- BD hold & support media for 20 cycle reusability lead free ink.

## Process Indicator Tapes



## Process/Integrating Indicator Strips





# Biological Indicators



## Spore Strips

For sterility testing in various sterilization environments. (Steam, EO, LTSF, Ozone)

## MagnaAmp® 1ml Spore Ampoule

Self-contained biological indicators ampoule with negative control for monitoring steam sterilization of liquids in containers or washer sterilizers.



## ProSpore® 4ml Spore Ampoule

Intended for use in the monitoring of saturated steam sterilization cycles at 121°C without negative control.

## SterilAmp II & 5230®

A compact, self-contained biological indicator for monitoring industrial steam sterilization of liquids in small containers Capsule for Steam & LTSF.



## ProLine Tubing Validation PCD

BI system designed for use in the validation or monitoring of steam sterilization cycle of tubing.



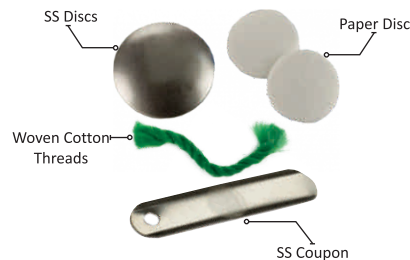
## EZTest®

### Self Contained Plastic Vials

Self-contained biological indicator intended for use in the monitoring of saturated steam, ethylene oxide and hydrogen peroxide sterilization.

## Industrial Use BI's

Mesa offers a line of industrial use BIs to address the unique requirements of the medical device and pharmaceutical industries.



## DriAmp®

### Spore Ampoule for Dry Heat & Depyrogenation

Appropriate for either high temperature direct air exposure or submersion in oils and other non-water based solutions where traditional paper strip indicators are difficult to use. Can be used for depyrogenation.

## Apex® EZTest®

Self contained BI for  $\text{H}_2\text{O}_2$ . Easy to culture no-laboratory required. Dramatic Color Change. Available in ATCC® 12980.



## Apex® BI for VHP

BI for Hydrogen Peroxide ( $\text{H}_2\text{O}_2$ ) vapor sterilization offering stainless steel discs and ribbons. Available in variable population ( $10^3$  to  $10^6$ ). ATCC® 12980 & 7953

# Products for SIP Validation

## Spore Suspension

Calibrated suspensions of bacterial spores appropriate for direct inoculation of products for monitoring steam, ethylene oxide, dry heat, hydrogen peroxide, radiation and other sterilization processes.

- Available in  $10^3$  to  $10^8$ .
- List of Bacteria :
  - *Geobacillus stearothermophilus* (reference # 7953, 12980)
  - *Bacillus atrophaeus* (reference # 9372)
  - *Bacillus pumilus* (reference # 27142)
  - *Bacillus subtilis* "5230" (reference # 35021)
  - *Bacillus subtilis* (reference # 6633)
  - *Bacillus smithii* (reference # 51232)
  - *Clostridium sporogenes* (reference # 11437, 19404 or 7955)



## Silicon Tri Clamp Gasket for Pro-Test

Product that enables the use of a self contained biological indicator in sanitary process lines. Permits either top loading or inline positioning of EZTest® self contained biological indicator.

- Time Saved
- You can feel secure knowing that the biological indicator will not be lost down steam in the process.
- Easy Retrieval.
- Available for 0.5", 1", 1.5" & 2".
- No problematic laboratory transfer.

## Types

- Silicon Tri clamp Gasket for Pro-Test
- Single Port Silicon Tri clamp Gasket
- Silicon Tri clamp Gasket for BI (Strips)
- 4 Port Silicon Tri clamp Gasket



Single Port Silicon  
Tri clamp Gasket  
for EZTest



Sanitary Spore Traps  
Inline validation is easy  
with spore traps



Smart Gasket  
For product sampling  
devices offers 1-4  
ports for product  
sampling during  
processing



SS Clamp

## Steam Quality Test Kit



- Non Condensable Gas
- Dryness Factor
- Super Heat

Steam quality test equipment to qualify plant/utility/clean/pure steam generators, steam distribution systems and steam supplies.

## SQ2 Sanitary Sample Coolers



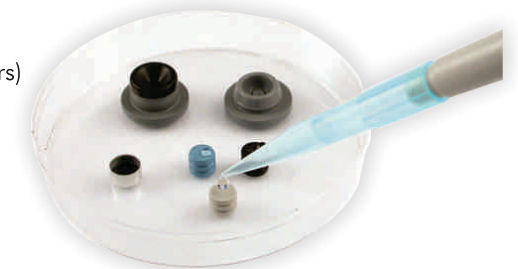
- Fixed Type
- Portable Type

KSA manufacture the SQ2 sanitary sample cooler specifically for the safe taking of high quality chemistry/TOC.

## Testing & Services (D-Value) by MesaLabs

Mesa Labs can inoculate & perform D-value analysis on small items (e.g. coupons or stoppers)

- Product D-Value.
- Stability D-Value.
- Stability Pooled Assay.



## Quantitative ATCC® Culture for GPT



- Ready to use ATCC® culture.
- No serial dilution required.
- 10-100 CFU/0.1 ml population.
- 43 different strain available.
- Quick dissolve & product with digestion time for better recovery .
- ATCC® 25416 & ATCC® BAA-245 is now available.
- Available - Pellets with hydrating fluid.

## Basic different...

### EZ-CFU Single Step

- ATCC® Derivative.
- 3rd passage from reference culture
- 1vial of 1.2 ml hydrating fluid + 1 lyophilized pellets .
- Stable at 25°C for 5 days during transportation.
- Storage at 2°C to 8°C.
- Detailed COA is provided with ATCC® reference & Mean Assay Value of CFU.
- MBL mentions Gram Identification Method & VALTEK or MALDI Identification Method in COA.

### Competitors

- NCTC® Derivative.
- 4th Passage from reference Culture
- 1.1 ml suspension is generated from 1 pellets.
- Highly temperature sensitive transportation is below 0°C
- Storage at -20°C.
- COA provided with NCTC® reference & Mean Assay Value of CFU.
- Organism identification method is not mentioned in COA.

## Qualitative ATCC® Culture

- Ready to use ATCC® Cultures stik & pellet format.
- Convenient storage at 2°- 8°C.
- COA with detailed strain information.
- FDA approved.
- Available in :
  - Lab-Elite CRM (Certified Ref. Material)
  - Kwik Stik Plus (2nd Passage)
  - Kwik Stik (3rd Passage)



## Environmental Isolate

- Customize product with population Range 10 to 100 CFU/0.1 ml to 10<sup>8</sup> CFU.
- Local strain in lyophilized pellet.
- Environmental & water isolates.
- Genotypic & phenotypic identification services.
- Microbiologics can store your strain up to 4 years.
- Special packaging for sending the isolates.

## Antimicrobial Effectiveness Test (AET)

- Accredited reference material under ISO 17034 standard.
- Delivers 1.0x10<sup>5</sup> to 1.0x10<sup>6</sup> CFU per ml of product tested.
- Strains are less than or equal to three passages from the reference culture.
- Ready-to-use format saves time and money.
- Refrigerated storage is easy and economical for isolates.





# Ready to Use Media Plates

It is one of the most prestigious project of JUNE ENTERPRISES, under the brand of JECLIN.

Manufacturing location follows all pharma standards, along with all SOP's in place and most importantly minimum contact of humans to avoid contamination during manufacturing itself. Production area maintains ISO class 7 and Lab area follow standard practices of GLP.

As a reputed supplier of various validation products we are open for audit of our manufacturing location. Plant capacity is to produce max 3000 plates per hour and due to flexibility we can BESPOKE manufacturer of any media.

- Petriplate with SCDA (TSA) media.
- Plates with size 90mm & 55mm dia.
- Shelf life 6 months.
- Custom orders for selective media (Bespoke Solution).
- High quality dehydrated media.
- Choice of media (e.g. Difco, Neogen).
- Gamma irradiated triple bagged.
- Manufactured in cleanroom with GMP standards.
- Available with validation guide.
- Sterility and growth performance tests on all lots.
- COA with irradiation certificate.
- With or without additives e.g. Glycerol, Polysorbate 80.
- Modern state of art manufacturing.
- Available with Lid-Lock system.



**Lid- Lock System**



## 16" Gloves

### Sterile & Non-Sterile Latex

Offering comfort, flexibility and elbow length protection, the 400mm (16"). Latex Glove 16" is the natural choice with a textured surface for enhanced grip, the ambidextrous, natural-colour glove is powder-free and double-donnable.

#### Product Information

- Sterile latex cleanroom compatible.
- 100% natural latex.
- Powder-free.
- Natural colour.
- Elbow length 400mm (16").
- Ambidextrous.
- Textured palm & fingers.
- Protein level less than 50µg/g.
- Double-donnable & excellent fit.
- Gamma irradiated.

#### Quality Assurance

- Standard : ISO 11137-3.
- Gloves sterility testing perform as per ISO 11137-3, ISO 11737-2 and USP 71 standards.
- Manufactured in facility operating under ISO 9001 & 13485 quality management systems.
- Processed in a NEBB certified ISO class 5 cleanroom.
- Physical properties comply with European medical glove standard EN455-2:2015.

#### Shelf Life

- Three years from date of manufacturing.

#### Packaging

- One pair per inner PE wallet, One PE wallet per sealed PE pouch, 10 pouches per PE bag, 20 sealed PE bags per lined carton (200 pairs).



## Isofield 24" Gloves

### Sterile Latex

#### Product Information

- GMP Grade A compatible.
- ISO Class 4 & 5 compatible.
- Sterile Latex.
- Natural colour.
- Shoulder length 600mm (24").
- Textured palm & fingers.
- Protein level less than 50µg/g.

#### Quality Assurance

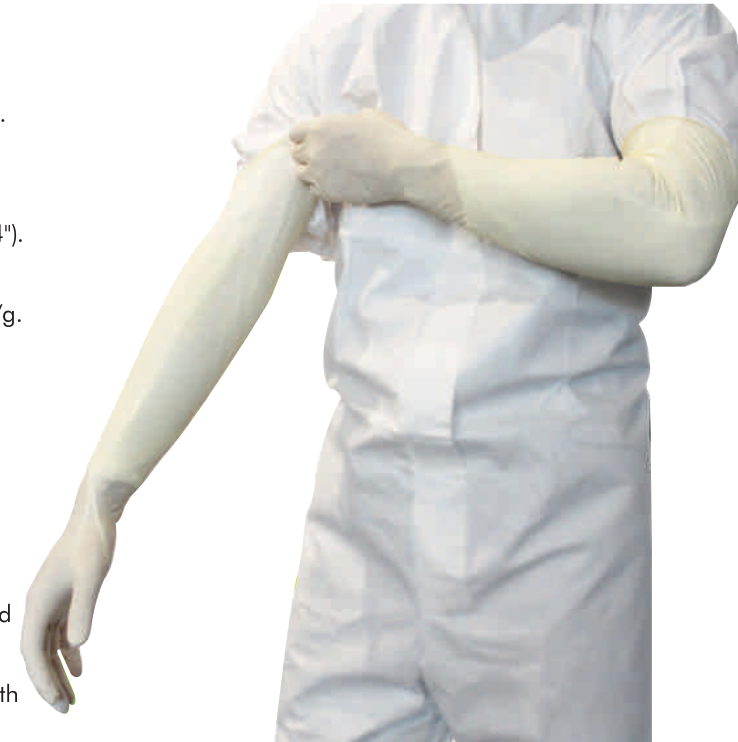
- Manufactured in a facility operating under ISO 9001:2015 quality management system.
- Processed in a NEBB certified ISO class 5 cleanroom.
- Physical properties comply with European medical glove standard EN455-2:2015.

#### Available

### 12" & 16" Gloves - Sterile & Non Sterile



- Elbow length 400mm (16") & 300mm (12").
- Sterile & Non-Sterile.
- Latex & Nitrile.



## Reusable Garments

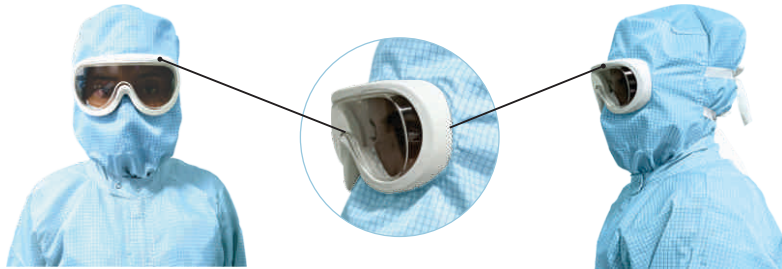
Introducing Autoclavable/Reusable garment manufacturing in our own facility. Garments are validated & tested in NABL certified leading textile institutes. Made from 98% polyester and 2% carbon filament, hence it has anti-static properties.

Garment tested in NABL® for following :

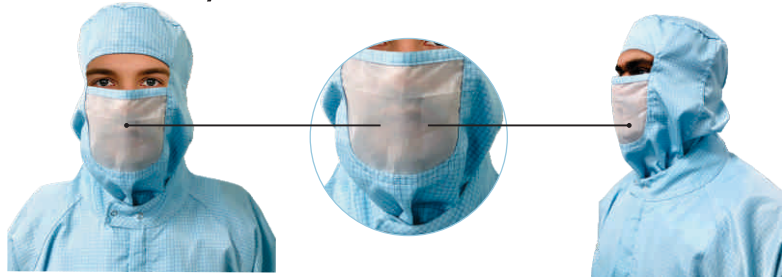
- Washing cycle at 60°C.
- Autoclavable cycle at 121°C.
- Water absorbency of fabric.
- Particle Filtration & Helmke Drum Test.
- Blend % of fabric.
- Tensile at high strength-strip.
- Tearing strength, air permeability & zipper strength of fabric.
- Statimat-M (single yarn strength & elongation, RKM from spool).
- Surface resistance/electrostatic/antistatic.
- Pore size.
- Seam strength of garment.
- Appearance after dry cleaning (one wash).
- Martindale abrasion up to 40,000 rubs.
- Lot COC.
- Available with RFID.



### Hood with Attached Goggle



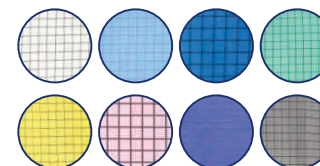
### Hood with Nylon Mesh Fabric



UZIP - EASY TO WEAR



### Fabric Colors



\* Colors are for representation purpose only.



# Personal Protection



## Disposable Garment

Garment is designed and manufactured from two layer spunbond combined with three layer meltblown nonwovens inside (SMMMS) suitable for use in either a sterile or non-sterile cleanroom environment, providing a full head-to toe coverage solution in a variety of combinations, the range includes coverall, hoods, overboots.

Garment tested for following:

- Anti-static, lightweight, low-linting, clean, tough material.
- Thumb loops to ensure a secure hold.
- Zip with sealable cover.
- Elasticated back, cuffs and ankles.
- Gamma irradiation indicator on individual garment.

## Cleanroom Reusable Socks

- 85% Polyester, 10% Nylon & 5% Spandex.
- One size Fits all.
- Cleanroom compatible
- Washable to up to 5 times.
- No lint & particle generation.
- white.
- Manufactured & packed in cleanroom.

**Also available Disposable Socks with 100% Polyester**

## Cleanroom Shoes: Dual Sealed Goggles

- Available in autoclavable or washable.
- Material : TPE & EVA.
- Unisex.
- Anti-static & slip resistance.
- Available in with & without straps and colors.



- Specifically designed for clean room application.
- Can be autoclaved.
- Top-Vented body with clear uncoated lens.
- CE Certified.
- Complete with extra wide grey, latex free neoprene strap.



## ALPHA(without mask) & BETA(with mask) Sterile Kit

- Sterile disposable coverall with mandarin collar, hood & overboots with sealable zip flap
- low-linting & antistatic fabric.
- Anti slip PU sole.
- GMP Grade A & B and ISO Class 4 & 5 cleanroom compatible.
- Also available hood with integrated facemask.
- Processed in a NEBB certified ISO Class 5 cleanroom.
- Tested for chemotherapy drugs.
- Complete validation test report available.



## Isoclave Autoclavable Goggles

- Grade A / ISO Class 5 compatible.
- Indirect upper and lower ventilation.
- Panoramic visibility.
- Fits over standard prescription glasses.
- Ergonomic frame with flexible nose skirt to ensure secure fit.
- Premium anti-scratch, optical grade, anti-fog lens.
- Frame & lens tested to withstand 40 autoclave cycles.



## Isofield PRO Shoes

### GMP Compatible Safety Shoes

- Designed for GMP environments.
- Lightweight and comfortable.
- Anti-static insole and outsole.
- Protective composite toe-cap.
- White colour.
- Easy clean outsole for contamination control.



# Mopping System

## Quick Task™ -Flat Mopping System

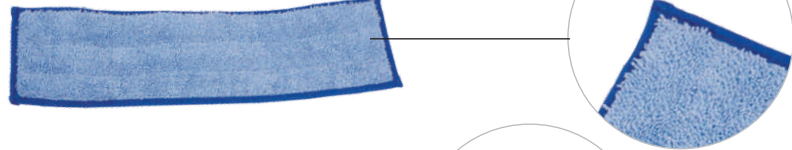
- Mop heads variety-knitted polyester, polyester/cellulose, microfiber/foam & microfiber.
- Sterile & non-sterile, single use mop heads.
- Can be repeatedly laundered & autoclaved providing exceptional values.
- Choice of hardware stainless steel & polypropylene.



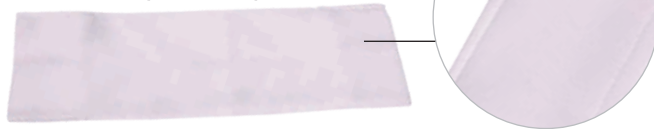
Knitted Looped Polyester Mop Head



Looped Microfiber Mop Head



Knitted Polyester Mop Head



Microfiber Face & Foam Core Mop Head



## Vertiklean® - Wall Mopping System (T-Mop)

- These lightweight, polyester disposable mops.
- Excellent for applying disinfectants & for wet cleaning of vertical surfaces, ceilings & walls in controlled environments.
- Ideal for reaching awkward corners & ceilings with a complete range of motion.
- System are compatible with gamma, ETO & autoclave sterilization.



Vertiklean® Max™

## Easysat® Bucketless Floor Mop

- The solution tank holds up to 1.5 L & cleans up to 5,000 square feet.
- A snug-fitting lid minimizes exposure to chemicals.
- Lightweight mop system weighs only 3.2 kg with a full tank.
- Trigger flow control mechanism releases cleaning solution on demand or continuously.
- Design for cleanroom, easy to use, autoclavable & avoid disinfectant wastage.



## Self Wringing Mopping System

- Ideal for fast & easy handling, cleaning or disinfection of floors, walls & ceiling.
- Autoclavable.
- No Wringer Required.
- Polyether foam for better absorption.
- Polyester foam mop with microfiber laminate for better adsorption & particle migration.
- Perfect mop with right balance of absorption & cleaning of contaminants.



# Mopping System

## Edgeless® - Floor Mopping System

- Mops are made from a continuous tube of 100% polyester knitted fabric looped to form tubular mop strands that will not shed or break.
- Designed for wet/damp mopping.
- Rugged polyester construction is ideal for tough cleaning tasks.
- Compatible with a wide range of chemicals & disinfectants.
- Repetitive autoclavable.



## EasyReach™ Cleaning Tool

- 360° rotational mop head.
- Available Pre-saturated with sterile 70% IPA & presterile.
- Recommended for effective cleaning & disinfection of surfaces in :
  - For isolators, cabinets.
  - RABS.
  - Filling lines.
  - Laminar air flow hoods.
  - Bio-safety cabinets.
  - Glove boxes.
  - Incubators.

## Dual Clean™ Curtain/Softwall Strips Cleaner

- Modular soft-wall enclosures & cleanrooms.
- Soft curtain barriers in pharmaceutical & biomedical manufacturing.
- Segregated clean work cells.
- Controlled condition warehouses.
- Compounding pharmacies.
- Contamination sensitive laboratory process.
- General production areas where cleanliness is important.



# Non-critical Area Cleaning

## Squeegee

- Combines optimum hygiene with effective water removal from walls, floors and table surfaces.
- The angled blade allows the squeegee to remove water from corners and other difficult to reach areas.
- Color coded.
- Can be autoclave/steam wash at 121°C.



## Water Gun

- Suitable for cleaning floors and machinery including rinsing off work surfaces and walls after chemical foaming.
- Squeezing the rubber insulated trigger determines the Jet pattern.
- The Water Jet can also be adjusted using the screw at the end of the gun.

## Mops & Mopping System

- Cleaning mop for non critical area specially for warehouse & corridor.
- Reusable microfiber & polyester flat mops.
- Color coding available.
- Upto 400 cycle washable\*



# Bucket/Trolley Systems

- June offers a variety of mopping bucket systems made from 100% stainless steel
- Trolley with stainless steel or poly propylene buckets (2 or 3 bucket systems).
- With & without down press wringer & slinger.
- Autoclavable.
- Lightweight & easy-to-manoeuvre.
- Buckets available in various capacities.
- Durable stainless steel components.
- Autoclavable at 121°C for up to one hour.
- Compatible with all common disinfectant solutions and most common solvents.
- Highly polished by mechanical or galvanic means for excellent biologic control.
- Available locally made & imported.



## Accessories



SS Bucket Lid



SS Bucket



PP Bucket



SS Flat Mop Slinger



SS Flat Mop Wringer



# Disinfectants



## Sterile 70% IPA with WFI - RTU

- A blend of 70% v/v isopropanol with 30% water for injection or purified water.
- Guaranteed endotoxin levels of <0.25EU/ml.
- The alcohol blend is 0.2 micron filtered, filled and bagged in a Grade C (ISO Class 7) cleanroom.
- Sterile - irradiated at 25 kGy.
- Trigger sprayer and "bag in bottle" protected system.
- Ready to use with 3 year shelf life.
- Tripped bagged in polyethylene linear tear bags.



## Sporicidal Disinfectant (Prochlor) - RTU

- A blend of hypochlorous acid in EP purified water is a revolutionary new sporicide achieving a 100% kill against spores in under 1 min.
- Log 6 kill against Bacillus subtilis in 60 secs saves time spent on bio decontamination.
- Ready-to-use and is efficacious against bacteria, fungi, molds, yeasts, viruses and spores.
- Filtered to 0.2 microns in a Grade B cleanroom ensures the product is free from contamination and particulates.
- Supplied as either trigger sprays for small areas or 1L and 5L capped containers for when larger volumes are required.

## Sterile 6% Hydrogen Peroxide - RTU

- HydroPure is a blend of 6% hydrogen peroxide and water for injection or purified water.
- Sporicidal in 15 mins.
- Non-sterile version available.
- Filtered to 0.2 microns under Grade A airflow in a Grade B cleanroom.
- Guaranteed endotoxin level of less than 0.25 EU/ml.
- Trigger spray - triple bagged in polyethylene linear tear bags.

## Autoclavable Spray Bottles

- For sterile IPA/disinfectants.
- For pharmaceutical production, QC testing and clinical laboratory.
- Improved design for 40/70 cycle autoclaving.
- All components are heat resistance and autoclavable.
- Can be used for JET or MIST.
- Flexible deep hose & can be used in any angle.



## Sporicidal Disinfectant (Peridox RTU™)

- Unique blend of hydrogen peroxide & peracetic acid.
- Broad spectrum, one application disinfectants & hard surface cleaner.
- Patented hyperactive chemistry gives log 3 reduction against bacterial & fungal spores in 3 mins.
- Has excellent material compatibility so will not damage common cleanroom materials.
- Push/pull cap eliminates droplets reducing the risk of inhalation.
- Can be easily applied to a wipe or cleaning tool.

## NeutraKlean - Neutral Detergent Concentrate

- 7.5% amine oxide in purified water (EP) (dilutes in 5L of water to create a ready-to-use detergent of 0.3% amine oxide).
- Concentrate with a 2 year shelf life.
- 0.2 micron filtered under Grade A airflow in a Grade C cleanroom.
- Gamma irradiated at no less than 25 kGy.
- Provided as a unit dose concentrate, Contec NeutraKlean Concentrate is designed to be diluted in 5L water of suitable quality.



# Cleanroom Dry Wipes

## Nonwoven Wipes

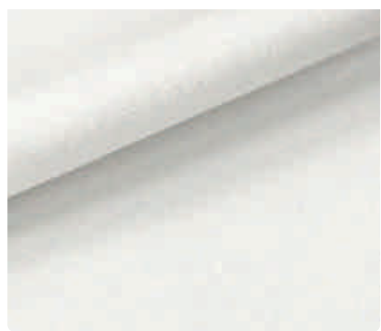
### Sterile & Non-Sterile

- The Non-woven wipes are used in a wide range of applications, from general industrial use to critical applications in pharmaceutical, medical device and aerospace industries.
- Contec offers many non-sterile and sterile non-woven wipes, both dry & presaturated excellent general-purpose wipe.
- Sorbency with all liquids.
- Maintains strength in wet and dry applications.



## Amplitude™ EcoCloth™ (56 g/m<sup>2</sup>)

- Hydroentangled lightweight nonwoven wipe.
- Blend of 54% cellulose & 46% polyester wipe provides an economical absorbent wipe ideal for general cleaning applications.
- Economical and cost effective.
- Lightweight, excellent durability & sorbent wipe.
- Double packaged to preserve product integrity.



## Amplitude™ Sigma™ (67.7 g/m<sup>2</sup>)

- Hydroentangle 58% Cellulose/42% Polyester wipe.
- Blend of 58% cellulose and 42% polyester staple fibers.
- The Sigma wipe is strong & durable even when wet.
- Low in extractable residues & particles.
- Outstanding sorbency & is an excellent all-purpose wipe.



## Knitted Polyester Wipes

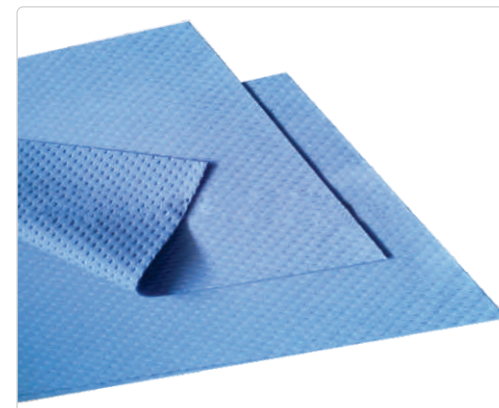
### Sterile & Non-Sterile

- Polyester knits are the cleanest category of wipes for critical environments and are therefore the most widely used wipes in ISO Class 3-4 cleanrooms.
- These wipes are made from multi-filament textured polyester yarns that are low in particle generation and high in abrasion resistance.



## 2-Ply Quilted® I Wipe (Higher GSM)

- Allows more than double the sorbency of single-ply fabrics.
- Laser cut non-shedding, non tearable & durable.
- Safe for most critical applications.
- Excellent sorbency with solvents.
- Abrasion and chemical resistant.



## Low GSM Wipes

### 1. Sealed Edge

- Anticon Guardtrail G2, Anticon Gold, Polynit Heatseal, Polywipes-C Heatseal.
- Achieved via laser sealed edges or sealed-border technology.
- Reduced particles, fibers, NVR'S and ionic contamination.
- Three packaging options: stacked, bulk and folded.
- Controlled bio-burden for post processing terminal sterilization.

### 2. Treated

- Anticon Gold standard weight with PAT, white magic with PAT.
- Greater volume of particles removed from the surface being cleaned.
- Improves performance of polyester.
- Allows polyester to sorb water based solutions.
- Reduced particles, fibers, NVR'S and ionic contamination.





# Presaturated Wipes

## PROSAT® Sterile™ Polynit Heatseal Wipes

100% no-run interlock knit polyester wipes presaturated with 70% IPA & 30% WFI

- Made from filament polyester that is laser-cut to bond the fibers at the edges of the wipe.
- Non-abrasive edge that allows full utilization of the wipe surface.
- Chemical resistant and exceptionally low in particles and extractable residue making it ideal for general purpose and critical cleaning.
- Presaturation greatly reduces solvent usage, reduces VOC's associated with IPA and maximizes process control and consistency.
- Validated sterile per ISO11137 guidelines to a 10<sup>-6</sup> SAL.



## PROSAT® Sterile™

### Polywipe-C Heatseal Wipes

- Made from a standard weight 100% knitted.
- Chemical resistant & extremely low levels of particles and fibers.
- Blend of presaturated with 70% USP grade isopropyl alcohol & 30% DI water
- Validated sterile to a 10<sup>-6</sup> SAL per ANSI/AAMI/ISO 11137 guidelines - suitable for use in grade A/B cleanrooms.
- Heat sealed edges - prevent fiber generation during use.
- Resealable pouch - preserves cleanliness and solvent saturation levels.
- Small number of wipes per resealable pouch eliminates waste.
- Sterile & non-sterile version.



## SATWIPES® Wipes

Polyester/rayon nonwoven wipes presaturated with 70% IPA

- The wipes are presaturated with 70% IPA and 30% deionized water.
- Convenient center-pull container when large volumes of presaturated wipes (700) are needed.
- Made of 50% polyester and 50% rayon nonwoven material.
- Soft, durable wipe.
- The fabric is strong and sorbent.
- Eliminates the need for in-house blending
- Formula dries quickly leaving the surface ready for the next process.
- Low linting.
- Economically priced.



# Pharmaceutical Silicon Tubing & Assembly



## Types

- APST : Unreinforced Silicone Tubing.
- APHP : High Pressure Unreinforced Silicone Tubing.
- APSPG : Pump Grade Silicone Tubing.
- APSH : Braid Reinforced Silicone Hose.
- APSH-DB : Double-Braided Silicone Hose.
- APSW : 4-Ply, Wire-Reinforced, Mandrel-Wrapped, Silicone Hose.
- APFOS : Stainless Steel Overbraided PTFE Hose.
- APEWF : Wire Reinforced EPDM Hose.
- GORE® STA-PURE® Pump Tubing : Series PCS; For Single-Use Peristaltic Pump.

## Specifications

- Particulate testing as per USP 788.
- NFS 51 certified.
- DMF # 26598.
- Documented to lot traceable with batch label on each bag.

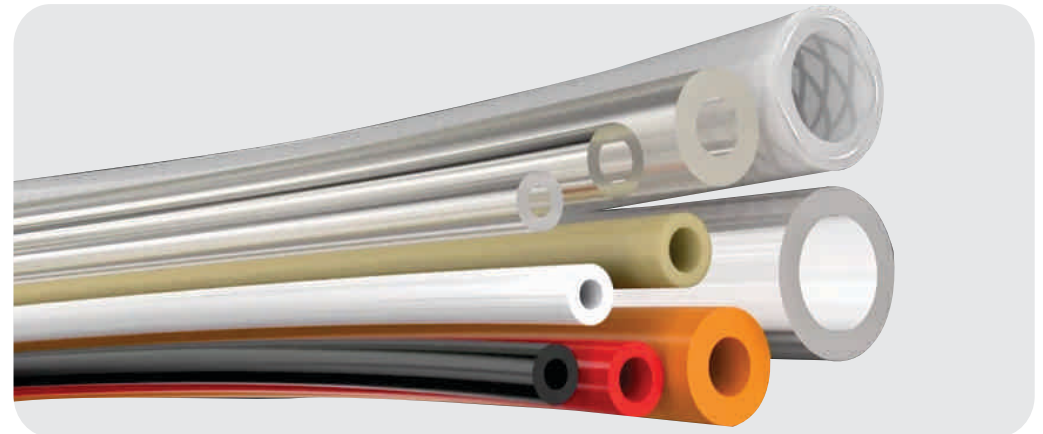


ELDON JAMES

## Fittings, Connectors & Tubing

### Types

- Bag Ports
- Elbow Fittings
- Cross & Y - Fittings
- Tee Fittings
- Sanitary Flanges
- Couplers
- PVC Free Tubing



# Hose Assembly



- **S.S. Corrugated Flexible Metallic hoses**
  - Temperature: -200°C to +700°C.
  - Size: 6mm(0.25") to 300mm(12").
  - Material: S.S. 316/304 & 304 Braiding.
  - Suitable for solvent, super heated steam & petroleum product.
- **PTFE Plain & Corrugated Hoses**
  - Temperature: -73°C to +260°C.
  - Material: Smooth inner core with S.S. wire braiding. Highly resistant to almost all chemicals.
  - Suitable for chemical, waste water & petroleum products.



# Cleanroom SS tools



Steritool is the leading source of stainless steel (306 or 316 or 420) hand tools for critical environment applications. All Steritool products are fully traceable through material heat & laser etched part numbers. Certificate of conformance, material and passivation are available upon request.

Steritool stainless steel hand tools are the solution to your aseptic or critical environment processing needs.

- Open End Wrench
- Combination Wrench
- Bench Press
- Torque
- Scissors
- Chisels
- Clamps
- Wire Cutter
- Sockets
- Hemostat Forceps & Tweezers
- Ball Pein Hammer & Hamallet
- Hex Keys (Allen Keys)
- Ice Pick, O-ring Tool, Pointer
- Knives
- Nut Drivers
- Pliers
- Tool Box & many more....





# Sterilization Packaging

**Tyvek®**

## Sterilization Reel

- The quality of see-through packaging made of Tyvek® and film is crucially influenced by the choice of materials.
- Used only the strongest medical grade of Tyvek®: Type 1073 B with 75 g/m².
- Excellent barrier properties against germs and moisture, extremely high puncture resistance
- Fiber-free peeling without delamination characterize this sterile barrier system.



**Hypak™**

## Sterilization Reel

- 100% High density polyethylene with biocompatibility.
- Hypak™ has passed the EU REACH and RoHS regulations test and no toxic and harmful substance included.
- Used only the strongest medical grade of Hypak™: Type H 107 5B with 75 g/m².
- Excellent barrier properties against germs and moisture, extremely high puncture resistance
- Fiber-free peeling without delamination characterize this sterile barrier system.

## Bowl Cover for Equipment

The priority in the selection of packaging materials, when components have to be transferred from grade B to grade A areas, is the ability to maintain sterility from the moment of sterilization until opening before use.

- Non-woven HDPE.
- Custom shapes and sizes.
- Tear and perforation resistant.
- Easy to apply and remove.
- Low particle release.
- Excellent microbiological barrier.
- Uniform steam penetration.
- Sterile irradiation products available.
- Ready for autoclave sterilization.



## Paper Reel (Peel Pouch/Sterilization Reel)

- Medical grade paper with 52/54µ film to give optimum seal strength.
- Developed considering highest quality paper & film on high-speed machines to meet current requirements of industrial users.
- Complies to industrial standards for packaging with indicators printed for steam & EO sterilization.
- Available 60 & 70 GSM paper.



## Wrapping Paper Green

- Crepe paper is manufactured from 100% medical-quality cellulose fibers and combines most economical wrapping with good drapability.
- Crepe is particularly suitable for the packaging of lighter instruments and sets.





# Cleanroom Consumables & Sealing



## Pen & Marker

- Cleanroom pens & markers have permanent ink with fast drying as well as fade and water resistance.
- Cleanroom decontaminated and packed in a triple bag, gamma irradiated.
- Each lot delivered with irradiation certificate.
- Available in blue & black ink.



## LDPE Bag

- Bag available in 50, 80 & 100 microns.
- Dust free area manufactured with virgin raw material.
- Can used to store products or waste disposal.
- Also available gamma irradiated .
- Double bagged.
- Various sizes available.



## Sealing Machine

- Impulse Sealer.
- Rotary Sealer without printing or with printing validation.
- Roll holder & cutter.
- Seal check strips available.
- Work station.
- Conveyor.

## Cleanroom Autoclavable Paper

- 75±3 GSM - A4 size cleanroom paper.
- Ultra-low particle generation, ultra-low extractable chemicals & metallic ion content.
- High tear & tensile strength.
- Good heat toner adhesion.
- Antistatic treated surface.
- Processed & double-bag packages.
- Smooth feeding & superior toner adherence in laser printers & PPC copiers.



## Autoclavable Rubber Band

- Made with non-latex synthetic rubber. High rubber content.
- Bright orange color for easy identification.
- Excellent band count per pound.
- Soft stretch to prevent carpal tunnel syndrome.
- Autoclavable.



## Teslin (Non-Tearable Substrate)

- PPG TESLIN® substrate is a microporous, dimensionally stable, highly filled, single-layer & polyolefin-based synthetic material.
- A non-abrasive inorganic filler comprises 60 percent of the weight & it is 65 percent air by volume.
- The porous, uncoated nature of the Teslin substrate absorbs inks, adhesives, coatings, laminates into its structure to form strong & interlocking bonds with the substrate.

## Autoclavable Cleanroom Tape

- Offer the highest level of cleanliness available for today's critical environment.
- Constructed of a durable vinyl backing.
- Strong rubber adhesive that can withstand the autoclave process.
- Easy to write on with a pen.
- Inspected and individually double bagged & sealed in cleanroom polyethylene bag.



## Polyethylene Medium-High Adhesion Cleanroom Tape

- Acrylic medium to high adhesive.
- Specifically for sealing wafer shipping boxes as well as cleanroom packaging and bag sealing
- leaves no residue.



## Floor Marking Tape

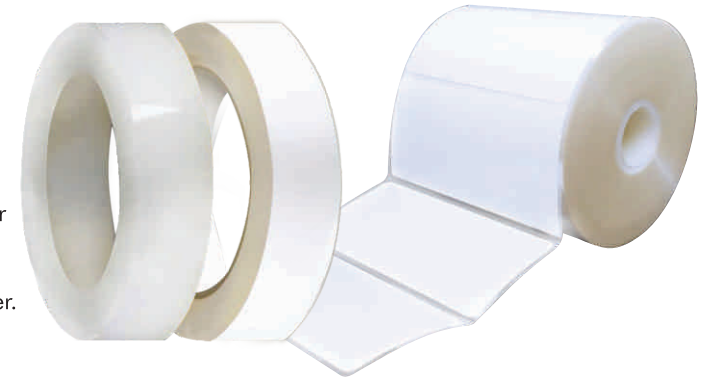
- Laminated Vinyl Tape.
- Highly durable floor marking tape designed to withstand high traffic and frequent cleaning.



## Cleanroom Tape & Label

The medium adhesion provides a strong bond and easy release making it perfect for maintenance and construction uses.

- Vinyl medium adhesion cleanroom Tape & cleanroom Label
- Chemical resistant, durable backing.
- Bright durable colors for floor and tool marking.
- Low residue.
- Easy to write on with a marker.
- Gamma irradiated.
- Standard sizes are available.



## Kapton-Polyimide Film Tape

Kapton Tape is made from DuPont® Kapton Polyimide film with silicon adhesive. It has been used in applications at temperatures as low as -73°C (-99°F) and as high as 260°C (500°F).

Features :

- Thin and conformable enabling masking of uneven surfaces.
- Removes cleanly without adhesive residue after exposure to heat.
- High strength backing provides superior resistance to puncture and tear.
- Resistance to chemical attack.



## Disposable Sampling Products

Burkle brand for high quality that have been specially designed & developed to optimally meet the demanding in part special requirements in laboratories, industry and science.  
The Burkle disposable samplers are used to take samples of liquids, viscous media, powders and granules.

### Characteristic as follows:

- Cleanroom Manufactured (Cleanroom Class 7)
- Complies with EU food requirements and FDA regulations.
- Disposable samplers, sterilized and sterile sampling containers and sampling devices for uncontaminated sampling.
- Optionally packaged individually and sterilized by gamma rays.
- For single use.
- White color.
- Documentation for TSE/BSE & cleanroom process.



Ladle - Long Handle



Sampling palette knife spatula



Long Handle Sampling Scoop



Scoops



Spatula with/without sleeve



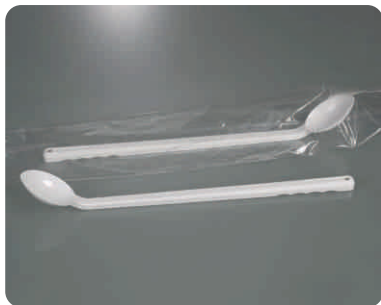
Sampling Spoon



Dosing Spoon



Disposable Forceps



Long Handle Spoon



Micro Spatula



Wide-necked Reagent Bottles



PET Sterile Bottle



Narrow Necked Bio Bottles PE



# Contamination Control Reusable Mat



## Clean Zone

- Dykem® Clean Zone is a high performance, antimicrobial mat or flooring suitable for pedestrian & light wheeled traffic.
- It is proven to be the most effective way of controlling all forms of foot, wheel & airborne contamination from entering critical areas up to 99.9%.
- Easy to clean, maintain & incorporate into existing standard operating procedures (SOP's).



## Disposable Sticky Mat

- "EFFECTIVE PARTICLE CONTROL" for critical area entrance.
- 30 numbered layers.
- Anti-bacterial, environmentally friendly water based acrylic adhesive.
- Available in 24" x 36" of size & blue color.
- Available with COC.

# Floor Marking Tape

Mighty Line offers durable safety floor tapes, floor signs, 5s floor markings and other 5s floor tape products for warehouses, corridors & labs.

- Quick easy application.
- Upto 3 years warranty (\*against manufacturer defects).
- 7 times thicker than average floor tape (50 mil thickness).
- Patented technology makes it more durable than other floor tapes.
- Beveled edges increases durability for forklift traffic.
- Peel & stick adhesive, removes easily.
- Available in 13 colors with footprints, arrows, angles, T's & dots.
- Withstands industrial brush scrubbers, forklifts and heavy industrial wheel traffic
- Mighty GLOW features a luminescent line centered on a tape that glows in the dark.
- Solid Colors: Yellow, White, Orange, Blue, Red, Green, Black, Brown, Grey and Purple available in Mighty Line floor tape.



# Does Your Contamination Control Strategy Need Product Comply To Annex 1?

## What is EU GMP Annex 1?

Annex 1 is a GMP document published by the European Commission and dedicated to the manufacturing of sterile product. All pharmaceutical companies that produce sterile products must comply with these regulations.

## What Does Annex 1 says?

### - Section - 7.13.I

#### - Goggle & Face Mask

Eye coverings & face should be worn to cover & enclose all facial skin.

### - Section - 7.13 & 7.16

#### - Sterile Glove

Sterile 400mm/600mm Gloves in Nitrile & Latex, double donnable, provide extra coverage of arm, no risk of gap between garment & gloves. Gloves compatible with alcohol & disinfectant comply with standard SOP.

### - Section - 7.11 & 7.13.I

#### - Disposable & Reusable Garment

Aseptically folded to comply with aseptic donning. Reusable garment should be subjected to qualification testing.

### - Section - 7.14

#### - Cleanroom Socks

Outdoor clothing (other than personal underwear) should not be brought into changing rooms leading directly to Grade B and C cleanrooms. Facility suits, covering the full length of the arms and the legs & socks covering the feet, should be worn before entry to change rooms for Grades B and C. Facility suits & socks should not present a risk of contamination to the gowning area or processes

### - Section - 4.33 & 4.34

#### - Disinfectant

Terminology of cleaning has been replaced with "cleaning and disinfection". Disinfection studies should be validated.

### - Section - 8.43

#### - Biological Indicator

Suppliers should be qualified and transportation & storage conditions should be controlled in order that BI quality is not compromised. The COA must be assessed for D-value & Z-value suitability

## How will June help you to comply with Annex 1?

Products manufactured by JUNE or Principle like MesaLabs(USA), Contec Inc.(USA), Isofield(Malaysia), Microbiologics(USA), AdvantaPure(USA), Eldon James(USA) etc. Comply to new regulatory standards & available locally.

# Something to Know

**Sterilization** describes a process that destroys or eliminates all forms of microbial life and is carried out in health-care facilities by physical or chemical methods. Steam under pressure, dry heat, Eto gas, hydrogen peroxide gas, plasma and liquid chemicals are the principal sterilizing agents used in health-care facilities. Sterilization is intended to convey an absolute meaning, unfortunately however some health professionals and the technical and commercial literature refer to “disinfection” as “sterilization” and items as “partially sterile.” When chemicals are used to destroy all forms of microbiologic life, they can be called chemical sterilants. These same germicides used for shorter exposure periods also can be part of the disinfection process (i.e. high-level disinfection).

**Disinfection** describes a process that eliminates many or all pathogenic microorganisms, except bacterial spores, on inanimate objects (Tables 1 and 2). In health-care settings, objects usually are disinfected by liquid chemicals or wet pasteurization. Each of the various factors that affect the efficacy of disinfection can nullify or limit the efficacy of the process.

**Cleaning** is the removal of visible soil (e.g. organic and inorganic material) from objects and surfaces and normally is accomplished manually or mechanically using water with detergents or enzymatic products. Thorough cleaning is essential before high-level disinfection and sterilization because inorganic and organic materials that remain on the surfaces of instruments interfere with the effectiveness of these processes. Decontamination removes pathogenic microorganisms from objects so they are safe to handle, use or discard.

**Thermal Death Time (TDT)** is the amount of time that is necessary to kill a specific number of microbes at a specific temperature. This value is obtained by keeping temperature constant and measuring the time necessary to kill the number of cells specified.

**The D-value** which denotes the decimal reduction time, is the time required at a specific temperature and under specified conditions to reduce a microbial population by one decimal. The decimal reduction time is dependent on the temperature, the type of microorganism and the composition of the medium containing the microorganism. Thus, after an organism is reduced by 1 D, only 10% of the original organisms remain. The population number has been reduced by one decimal place in the counting scheme. When referring to D values it is proper to give the temperature as a subscript to the D. For example, a hypothetical organism is reduced by 90% after exposure to temperatures of 300F for 2 minutes, Thus the D-value would be written as  $D_{300F} = 2$  minutes.

**The Z-value** is the increase or decrease in temperature required to reduce or increase the decimal reduction time by one decimal. It is a measure of the change in death rate with a change in temperature. The number of degrees Fahrenheit or Centigrade required for a thermal death time curve to traverse 1 log cycle. This is the temperature increase required to reduce the thermal death time by a factor of 10. The z-value gives an indication of the relative impact of different temperatures on a microorganism with smaller values indicating greater sensitivity to increasing heat. The z-value is obtained by plotting the logarithms of at least 2 D-values against temperature.

**The F value** for a process is the number of minutes required to kill a known population of microorganisms in a given food under specified conditions. This F value is usually set at 12 D values to give a theoretical 12 log cycle reduction of the most heat-resistant species of mesophilic spores in a can of food. For example, if there were 10,000 spores of a species of spore in a can of food and a 12 D process was given the initial 10,000 spores (10 spores) would be reduced to a theoretical 10 living spores per can or again in theory, one living spore per 10 cans of product (one spore per one hundred million cans). To refer to the original example where the D 240 was 1 min. the F value for the process would be 12 min. or  $F_{240} = 12$  min.

## Cleanroom Classification

ISO Classification Number(N)	Maximum allowable concentrations(particles/m <sup>3</sup> ) for particles equal to and greater than the considered sizes shown below						FED-STD-209E
	0.1 μm	0.2 μm	0.3 μm	0.5 μm	1.0 μm	5.0 μm	
ISO Class 1	10						
ISO Class 2	100	24	10				
ISO Class 3	1,000	237	102	35			Class 1
ISO Class 4	10,000	2,370	1,020	352	83		Class 10
ISO Class 5	100,000	23,700	10,200	3,520	832		Class 100
ISO Class 6	1,000,000	237,000	102,000	35,200	8,320	293	Class 1,000
ISO Class 7				352,000	83,200	2,930	Class 10,000
ISO Class 8				3,520,000	832,000	29,300	Class 100,000
ISO Class 9				35,200,000	8,320,000	293,000	

Class 4 - 550 Changes of air per hour

Class 5 - 350 changes of air per hour



# Notes



## June Enterprises Pvt. Ltd.

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