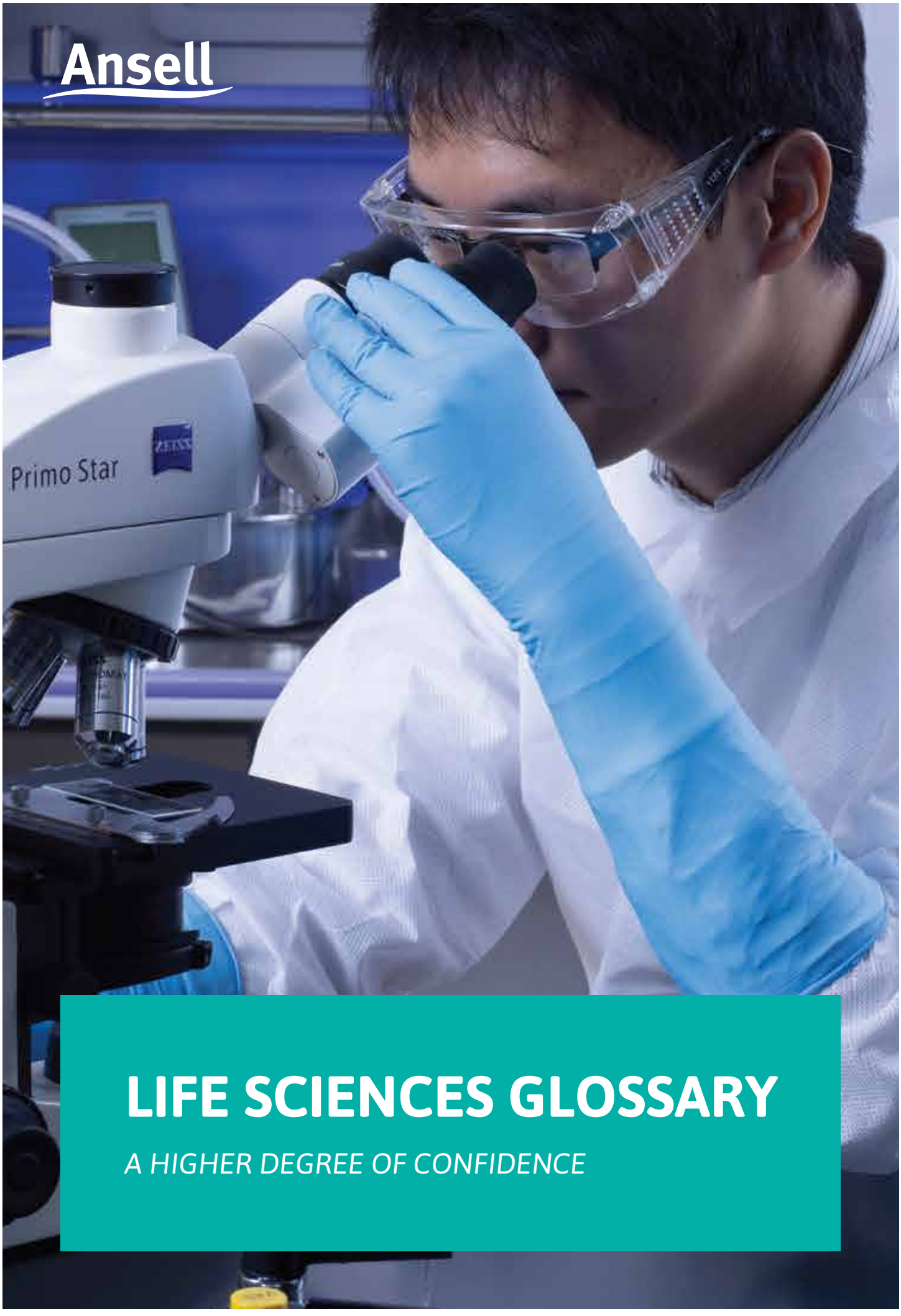


LIFE SCIENCES GLOSSARY

A HIGHER DEGREE OF CONFIDENCE

AAMI Association for the Advancement of Medical Instrumentation.

Accelerator-free Accelerators are chemicals added to glove materials in their liquid state to speed up the vulcanisation process. Some accelerators can cause an allergic reaction or sensitisation in a small number of users. Accelerator-free gloves are vulcanised without the addition of accelerators.

Aerobic bacteria Bacteria capable of growing in the presence of oxygen.

Agar A complex gel substance used as a medium for the laboratory culture of microorganisms which are seeded and grown on the surface of the gel.

Airborne particle Solid or liquid object suspended in air, viable or non-viable, sized between 1nm and 100 µm. Generally used with respect to Clean Rooms or Controlled Environments.

Allergy A hypersensitivity disorder of the immune system. Allergic reactions occur when a person's immune system reacts to normally harmless substances in the environment.

Anaerobic bacteria Bacteria capable of growing in the absence of oxygen.

Anion Ions are atoms which carry an electrical charge. An anion is a negatively charged ion.

Antistatic The property of a material which either prevents the build-up of static electricity or reduces its effects.

AQL Acceptable Quality Level is a statistical sampling method that defines the allowable number of defects for various sample sizes. The higher the AQL value, the higher the chance of having a defective glove.

Aseptic processing Handling sterile materials in a controlled environment, in which the air supply, materials, equipment, and personnel are regulated to control microbial and particulate contamination to acceptable levels.

ASTM American Society of Testing and Materials. The ASTM issues testing standards and specifications. The FDA utilizes many of the standards developed by the ASTM to establish medical device requirements.

Autoclave A chamber which is used to sterilise equipment and other articles by exposing them to high pressure saturated steam. The high pressure involved in the process means that the steam used is at a much higher temperature (typically up to 135ºC) than at normal atmospheric pressure (100ºC). The high temperature kills off viruses, fungi, bacteria and bacterial spores.

Autoclavable Equipment or other articles which are capable of withstanding autoclaving sterilisation process. Autoclavable products will normally have an appropriate autoclave cycle defined in their instructions for use, e.g. 121ºC for 20 minutes, 135ºC for 5 minutes, etc.

BFE Bacterial Filtration Efficiency is a measure of a material's resistance to penetration by bacteria or other microbes. The measure is applicable to breathable fabrics or membranes and is particularly relevant to face masks. BFE is expressed as a percentage and correlates with the ability of the fabric to act as a barrier layer; the higher the percentage, the better the barrier.

Bioburden The population of viable microorganisms on a raw material, component, finished product and/or package. It is expressed as the total count of bacterial and fungal colony-forming units (CFU) per single item.

BioTech Biotechnology is the use of biological processes, organisms, or systems to manufacture products intended to improve the quality of human life.

Cation Ions are atoms which carry an electrical charge. A cation is a positively charged ion.

CE mark Mandatory conformity marking for certain products sold within the European Economic Area (EEA). The CE marking is the manufacturer's declaration that the product meets the requirements of the applicable EC directives and Regulations.

Certificate of Analysis (CoA) for cleanroom gloves A validated document issued by the quality group housed in the manufacturing plant that certifies the quality and of the glove products being exported.

Certificate of Conformity (CoC) A certificate issued by the manufacturer to confirm that a specific lot or batch of product meets its declared specification.

Certificate of Irradiation (CoI) for cleanroom sterile gloves A validated document issued by the sterilisation plant that certifies the sterile cleanroom gloves as having been irradiated. Document includes the manufacturer lot & batch number, irradiation data, allowable dose range and actual dose.

CFU Colony Forming Units used for quantifying bioburden.
- Could be bacteria, moulds, yeasts or viruses.
- Used to monitor control measures during manufacturing and handling.
- Used to set irradiation doses in sterile validation.

Charge decay A method used to establish the antistatic properties of a material. A sample of material is held in an electrostatic field and the time taken for the charge on the material to decay away is measured. According to EN 1149-5, (Protective clothing- electrostatic properties – Part 5: Material performance and design requirements) a material is classed as antistatic if the time taken for the charge to decay to half of its starting value is less than 4 seconds.

Chemical degradation The degradation of a glove material resulting from exposure to chemicals. This attribute of gloves is measured according to the method described in EN 374-4 (Protective gloves against chemicals and micro-organisms – Part 4: Determination of resistance to degradation by chemicals). There are no Pass/Fail criteria for this test.

Chemical permeation The process by which a chemical moves through a protective glove material on a molecular level. Permeation involves the following:

- Absorption of molecules of the chemical into the contacted (outside) surface of a material
- Diffusion of the absorbed molecules in the material
- Desorption of the molecules from the opposite (inside) surface of the material

Chemotherapy The treatment of disease using chemical substances, especially the treatment of cancer by cytotoxic and other drugs.

Chlorination A process applied to gloves during manufacturing. Chlorination breaks down and removes any residual powder or other processing chemicals on or near the surface of the glove and is used to harden its surface. The level of "tack" on a glove surface can be varied by changing the level of chlorination – the lower the chlorination, the tackier the glove.

Cleanroom A cleanroom is a room or a facility in which the air supply, air distribution, filtration of air, materials of construction and operating procedures are regulated to control airborne particle concentrations to meet appropriate cleanliness levels.

ISO Classification number 14644-1	Class Limits (particles/m³) Maximum concentration limits (particles/m³ for particles equal to or larger than the considered sizes below						Federal Standard 209E Class
	0.1 µm	0.2 µm	0.3 µm	0.5 µm	1 µm	5 µm	
ISO Class 1	10	2					
ISO Class 2	100	24	10	4			
ISO Class 3	1000	237	102	35	8		Class 1
ISO Class 4	10000	2370	1020	352	83		Class 10
ISO Class 5	100000	23700	10200	3520	832	29	Class 100
ISO Class 6	1000000	237000	102000	35200	8320	293	Class 1000
ISO Class 7				352000	83200	2930	Class 10000
ISO Class 8				3520000	832000	29300	Class 100000
ISO Class 9				35200000	8320000	293000	

	CLEANROOM CLASSIFICATION		
ISO Classification	Class 4	Class 5	Class 6 or higher
Federal Standard 209E Class	Class 10	Class 100	Class 1000 or higher
Maximum Concentration limits (Particles/m³ of 0.5 micron)	350	3500	35000
Particulate Count (LPC) Counts/cm²	< 800	< 2500	> 2500

Contaminant Any unwanted substance on a garment or glove.

Controlled/Critical environment An area with defined environmental control of particulate and biological contaminants, constructed in a way that reduces the introduction, generation and retention of contaminants within the area.

Cytostatic Drugs Chemotherapeutic drugs (anti-cancer) capable of inhibiting cell growth.

Cytotoxic Toxic to living cells. Certain chemotherapy drugs and radiotherapy are both types of cytotoxic therapies.

DI water Deionised water has had almost all mineral ions removed to purify it. DI water is produced by a complex process of reverse osmosis and filtration.

Differential Pressure (Delta P) A measure of the breathability of a face mask. To measure the Delta P of a mask a sample is placed in a test rig and air is passed through it at a known flow-rate. The air pressure on either side of the test piece is measured and the Delta P is the difference between the two. The lower the Delta P, the easier it is to breathe. Making a facemask easier to breathe through by lowering its Delta P has an adverse effect on its bacterial and particle filtration efficiency.

Dose mapping In sterilisation by irradiation, dose mapping is a process employed to measure the distribution of the irradiation dose through the load being processed. Dose mapping is part of the sterilisation validation process, it verifies that the entire load will receive a lethal dose and establishes the points where the maximum and minimum doses are delivered. The max and min points are used for monitoring during routine processing.

Elongation During a tensile strength measurement, the percent of the length a glove material that can be stretched before it breaks.

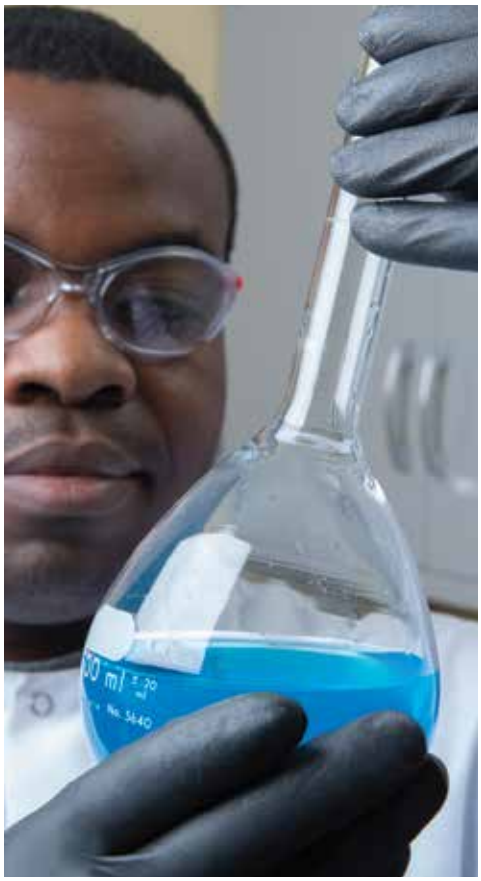
EN ISO 374 European standard which specifies the capability of gloves to protect the user against chemicals and/or micro-organisms. Tests conducted to acquire EN ISO 374 certification include permeation, degradation and penetration tests.

Endotoxins Toxins released by certain Gram-negative bacteria when they are lysed.

Ergonomics The scientific study of people and their working conditions, especially done in order to improve effectiveness. Ergonomically designed gloves and garments are designed to fit the worker and improve comfort by reducing muscle fatigue, increasing productivity and decreasing the number and severity of work-related injuries.

ESD properties The characteristics of a material which determine the way it performs when exposed to static electricity.

ETO sterilisation Also seen written as EtO or EO sterilisation. Sterilisation is achieved by exposing products to the lethal gas Ethylene Oxide. While ETO is a very effective sterilant it does have the drawbacks that the process is lengthy; product packaging must be permeable to the gas which has a cost penalty; and the removal of the gas post-processing is vital as ETO residues are carcinogenic, teratogenic and mutagenic.



Extractables Substances that can be removed from an article by a chemical or physical process. Extractables on cleanroom gloves are removed and analysed by washing with DI water.

Force at break (FAB) Force required to break a test sample of material under tension. FAB is measured in Newtons.

Gamma irradiation A common way of product sterilisation utilizing short wavelength electromagnetic radiation i.e. gamma wave radiation. Gamma irradiation is a clean and relatively fast method of sterilisation. Gamma irradiation has the benefit that the rays pass through most materials with relative ease which gives a wide choice of materials that may be used for product packaging.

GMP Good Manufacturing Practice is a system for ensuring that products are consistently produced and controlled according to quality standards. It is designed to minimize the risks involved in any pharmaceutical production that cannot be eliminated through testing the final product.

Good Manufacturing Practices (GMPs) Good Manufacturing Practices (GMPs) are regulations that describe the methods, equipment, facilities, and controls required for producing a consistent product.

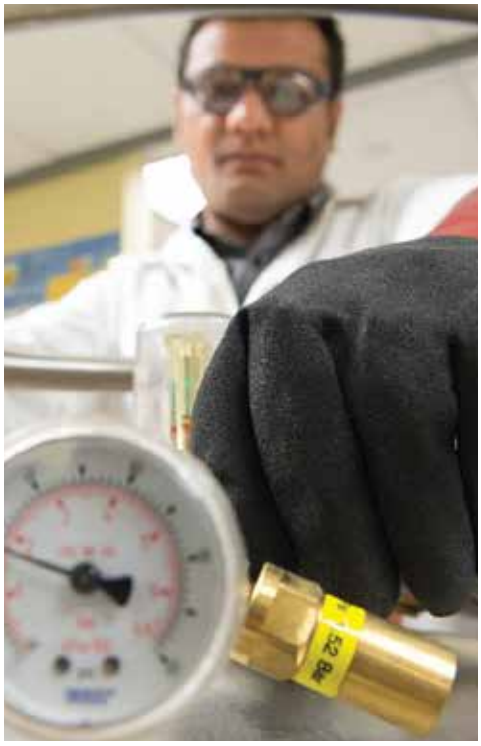
Helmke drum Test method used for determining the number of particles shed by cleanroom garments. The garment under test is tumbled in a rotating drum with a fixed airflow passing through it. The air leaves the drum via a particle counter to determine the number of particles shed per minute.

HEPA filters High Efficiency Particulate Air Filter (or sometimes High Efficiency Particulate Arresting Filter). Its efficiency is rated at least 99.97% efficient on particles of 0.3 microns in size. Used in controlled environments for maintaining the flow of uncontaminated air.

IEST Institute of Environmental Standards and Technology. A consortium that develops standards and recommended practices and provides training by industry experts. The standards and recommended practices are developed by committees comprised of scientists.

Ion Ions are atoms which carry an electrical charge.

ISO The International Organization for Standardization (ISO) is an independent, non-governmental international organisation with a membership of 161 national standards bodies, which originated in London in 1947. ISO has published a series of standards relating to Quality Systems known as the ISO 9000 family standards and standards related to product test methods and requirements.



ISO 11137-2: 2013 is the international standard for the sterilisation of medical products by radiation. Part 2 defines the methodology for establishing the sterilisation dose.

kGy Unit of measure for absorbed radiation dose. The Gray (Gy) is a derived SI unit and is defined as the absorption of one joule of radiation energy per kilogram of matter. The kiloGray (kGy) is used to report the radiation dose received by the load during Gamma irradiation. 1 kGy = 1,000 Gy.

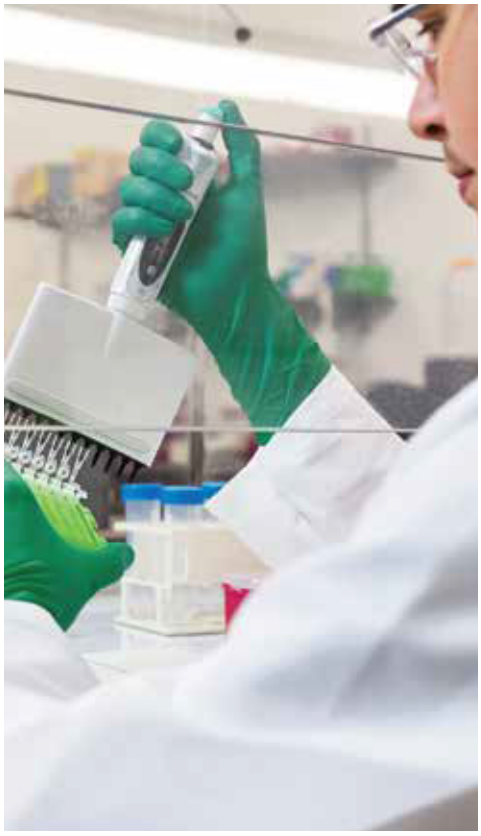
LAL Limulus Amoebocyte Lysate, a test method for the detection of endotoxins.

Laminar airflow The flow of air along a constant, turbulent free streamline. Laminar airflow is often used to create a localised controlled environment where HEPA filtered air is forced through a confined space to force particulates and other contamination downwards and out of the controlled area.

Latex Type I Hypersensitivity The most serious and the rarest form is an immediate and potentially life-threatening reaction, not unlike the severe reaction some people have to bee stings or peanuts. This form of allergy is normally associated with latex proteins. Latex allergies can be acquired over time due to repeated/prolonged contact with latex products.

Latex Type IV Hypersensitivity Also known as allergic contact dermatitis. Symptoms may include: redness and swelling, dry skin to patch eczema, and chronic sores that weep or bleed.

Leaching Process applied in the production of gloves by which chemicals or contaminants are dissolved and carried away by water to reduce chemical residual levels.



Life sciences Encompasses a broad array of disciplines such as Pharmaceutical manufacturing, Biotechnology, Medical devices and Academic institutions and Laboratories.

LPC Liquid Particle Count is a measure of the size and distribution of particles in a liquid. LPC is used for assessing the number of particles present on solid objects by analysing a set volume of eluent used to wash the object of interest. There is no correlation yet between particulate count of gloves and the clean room classification of clean room environments. Products are not classified, environments are.

Lysis The destruction of a cell by rupture of the cell wall or membrane. When certain gram-negative bacteria are lysed they can release endotoxins.

MBT Mean Breakthrough Time. Used to quantify the resistance to permeation by chemicals through gloves or other protective garments. During testing three test samples are examined to measure how long it takes for a test chemical to permeate from one side of the sample to the other. The reported MBT is the mean of the three test results.

Medical device Medical device means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

Micron A unit of measure equal to one one-millionth of a meter, represented by the prefix of the Greek letter mu, as µm and often shortened simply to µ.

Mil An American unit of measure equal to one one-thousandth of an inch. In the USA glove thickness is expressed in mils. 1 mil = 0.0254 millimeters. Typical single use gloves have single wall thickness ranging from 3 to 8 mil.

Nanometre A unit of measure equal to one one-thousand-millionth of a metre, represented by the prefix of the letter n, as nm.

Natural Rubber Latex A milky fluid obtained from trees and plants and is the raw material for manufacturing gloves.

Nitrile Nitrile rubber, also known as acrylonitrile butadiene rubber, and NBR, is a synthetic rubber copolymer of acrylonitrile (ACN) and butadiene used for the manufacture of cleanroom gloves. As an alternative to Natural Rubber Latex Nitrile has the advantage that it does not contain latex proteins providing an excellent alternative for individuals who have acquired a latex allergy. Nitrile gloves exhibit good puncture resistance, good chemical resistance and exhibit good ESD properties.

Nonpyrogenic Does not contain endotoxins which elicit a pyrogen response, e.g. inflammation, elevated temperature, fever, etc.

NVR (Non-Volatile Residues) Soluble material remaining after evaporation of a volatile solvent. Typically, organic or other components that do not evaporate at normal temperature and pressure.

Particle A small piece of solid or liquid matter usually measuring between 1nm and 1mm.

Particulate When used as a noun, particulate = particle. When used as a verb, to particulate = to shed particles.

Penetration Penetration is the movement of a chemical and/or micro-organism through porous materials, seams, pinholes, or other imperfections in a protective glove material or other barrier layer on a nonmolecular level.

PFE Particle Filtration Efficiency is a measure of a material's resistance to penetration by particles. The measure is applicable to breathable fabrics or membranes and is particularly relevant to face masks. PFE is expressed as a percentage and correlates with the ability of the fabric to act as a barrier layer; the higher the percentage, the better the barrier.

Polychloroprene A type of synthetic rubber which exhibits good stability and maintains good flexibility over a wide temperature range.

Polyisoprene A polymer designed to have the structure and attributes of natural rubber. It is synthesized to have minimal variation in properties from lot to lot, yielding better consistency than natural rubber.

PPE Personal Protective Equipment is any device or appliance designed to be worn or held by an individual for protection against one or more health and safety hazards.

Proposition 65 A Californian environmental control/public health control regulation. Prop 65 lists hundreds of chemicals which the state of California considers to be carcinogenic, teratogenic or mutagenic. Products that contain listed chemicals in excess of prescribed minimums are required to inform Californians on the product labelling e.g. "Warning: This product contains a chemical known to the state of California to cause cancer/be a reproductive toxicant".

Protein content Pertaining to natural rubber latex gloves, the measurement of total protein.

Pyrogen-free Claim made that, within the limits of detection, there are no pyrogens present on an item.

Pyrogen A substance, typically produced by a bacterium, which produces fever when introduced or released into the blood.

REACH (Registration, Evaluation and Authorization of Chemicals)
A regulation of the European Union, to improve the protection of human health and the environment from the risks that can be posed by chemicals. Being compliant with the regulation includes identifying and managing the risks linked to the chemicals used during manufacturing of gloves.

SAL Sterility Assurance Level. It is never possible to prove that all microorganisms have been destroyed during the sterilisation process, therefore sterility is claimed on the balance of probabilities. The SAL is the expected probability of an item being non-sterile after exposure to a valid sterilisation process.

- SAL 10^{-6} means that there is a statistical probability that one item in a million processed would be nonsterile.

Silicone-free Absence of silicone.

Sterilant Agent that destroys all microorganisms including bacterial and fungal spores.

Sterile Free from bacteria or other living organisms.

Sterile validation Testing and documentation to validate that a product is sterile at a selected dose.

- Product or manufacturing process changes require revalidation since the type or quantity of bioburden may have changed.

Sterilisation A physical or chemical act or process that destroys or eliminates all viable microbes.

Sterilisation dose Minimum absorbed dose required to achieve the specified sterility assurance level.

Sterilisation methods Gamma radiation, e-beam radiation, EO gas (ethylene oxide), autoclave (steam and pressure), dry heat, filtration, vaporized hydrogen peroxide (VHP).

- Method selection is a balance based on the degradation of materials and destruction of microbes.

Surface resistance A method used to establish the antistatic properties of a material. A pair of electrodes is placed on the surface of a sample of material and the electrical resistance between them is measured. According to EN 1149-5, (Protective clothing- electrostatic properties – Part 5: Material performance and design requirements) a material is classed as antistatic if the surface resistance is equal to or less than 2.5 x $10^{9}\Omega$.

Synthetic Not of natural origin; produced by chemical synthesis. Synthetic gloves include, but are not limited to vinyl (PVC), neoprene (polychloroprene), nitrile, polyisoprene.

Tensile strength Measurement of the force required to break a sample of material measured in Pascal (Pa) or MegaPascal (MPa). 1 MPa = 1,000,000 Pa. Tensile strength is calculated by dividing the force (in Newtons) by the cross-sectional area of the test sample (measured in square meters).

Terminal sterilisation A product in its final container is subjected to sterilisation.

VD Max VD max is one of the methods described in ISO 11137-2: 2013 for establishing and validating the sterilisation dose during Gamma irradiation.

Vinyl Polyvinyl Chloride (PVC) an alternative glove material offering a cost effective latex free alternative to nitrile and polychloroprene. Looser fitting than other glove materials they do not offer the same dexterity or protection but are well suited to certain applications.

Vulcanization The process of treating natural or synthetic rubber to impart elasticity, strength and durability.

The definitions provided in this glossary are not to be considered as definitive scientific or legal information.

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