Cleanroom Flooring

A Specifier's Guide

Gerflor

INTRODUCTION

Cleanrooms are essential in a growing number of industries to safeguard manufacturing operations and the quality of components, ensure the integrity of scientific research and maintain high levels of hygiene in healthcare settings. Some of the industries that feature cleanrooms include pharmaceuticals, manufacturing and high technology.

Against this backdrop, it is essential for architects and designers to understand how to design a cleanroom that meets high levels of cleanliness. There are many elements that contribute to designing a cleanroom, all of which must work together to achieve the desired result.

A range of cleanroom standards will apply to any given application, most importantly the project's industrial category needs to be considered. A pharmaceutical setting will have different requirements than a manufacturing setting. For example, cleanrooms can be segregated into two further groups: spaces that will contain hazardous materials and spaces that will not.

This whitepaper looks at the design considerations for cleanroom flooring, a very important aspect of a cleanroom facility. Flooring forms the internal base of the space and comes into direct contact with the total cleanroom environment, equipment, air and personnel. Flooring should be chosen carefully, keeping in mind the contamination-free approach and decontamination processes.

A cleanroom is a regulated space that is designed to control contamination such as biocontamination, airborne particles and vapours.

WHAT IS A CLEANROOM?

A cleanroom is a regulated space that is designed to control contamination such as biocontamination, airborne particles and vapours. Cleanrooms can be designed in a range of configurations, styles and classes, with the primary use being of controlled manufacture, or research and development applications. Given the exact requirements of such environments, cleanrooms are often custom designed and built for purpose.

The design and construction of cleanrooms are regulated by a set of standards (discussed further below). These standards specify the quantity of airborne particles of a certain size that are allowed within $1m^3$. Cleanrooms also control other environmental factors within the room, including temperature, biocontamination (bacteria), air pressure, conductivity, lighting and vibrations.

Sources of contamination include surfaces (e.g. walls, ceilings and floors), paints, coatings, debris and dust. Equipment and supplies may also affect the cleanliness of the environment, as well as hair, skin oils, perfume and clothing fibres.

Designers should note that, while specifying building materials and equipment that are fit for purpose is critical, these elements should be supported by appropriate work practices. For example, staff in a cleanroom need to observe proper contamination control and wear the appropriate clothing designed to trap contaminants that may be generated by the human body.

In some applications, the cleanroom will support work involving hazardous substances, such as liquid or solid chemicals or biological agents, in which case the protection of people is of the highest priority. These hazards are not only found in chemical, pharmaceutical and microbiological environments but also in certain manufacturing settings.

WHAT STANDARDS APPLY?

A range of industry bodies, associations and best practice guidelines reference AS/NZS ISO 14644 as the benchmark for cleanroom design. Designers should note that other cleanroom standards or requirements may apply, such as regulations set out by the Therapeutic Goods Administration (TGA) in relation to therapeutic goods.

Within Cleanroom flooring design, specific areas are critical including contamination management, resistance to external attacks, cleaning and decontamination and ESD properties. These areas are covered within ISO14644 and other noted standards such as:

ISO 14698 – Cleanrooms and associated controlled environments – Biocontamination control

ISO 22196 - Measurement of antibacterial activity on plastics surfaces

ISO 21702 – Measurement of antiviral activity on plastics and other non porous surfaces

ISO 846 – Evaluation of the action of microorganisms on plastics

ISO 2812 - a standard that specifies general methods for determining the resistance of an individual-layer or multi-layer system of coating materials to the effects of liquids, other than water, or paste-like products.

ISO 8690 - a standard that focuses on the measurement of radioactivity related to gamma ray and beta emitting radionuclides. Specifically, it provides a test method to assess the ease of decontamination of surface materials that may become contaminated by radioactive substances.

Good Manufacturing Practice (GMP) is another commonly referenced standard used mainly by medical and pharmaceutical manufacturers to ensure a controlled cleanroom environment. There are different codes of GMP, depending on the type of therapeutic goods or product, such as the GMP for Medicines and the GMP for Human Blood and Tissues. Australian medicine manufacturers are required to hold a license to manufacture from TGA demonstrating their compliance to the relevant GMP code.

GMP describes a set of principles and procedures that, when followed ensure the production of the highest quality of regulated goods. The Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (jointly known as PIC/S) safeguard cooperation in the field of GMP and related areas. They apply strict controls internationally in relation to the manufacture of therapeutic goods.

Companies in other industries may require cleanrooms that comply with specific standards which should be confirmed at the outset of the project. In some cases, cleanrooms will need to comply with several different standards in order to be considered compliant.

The floor is essential to maintaining a cleanroom environment because it is the primary surface on which contaminants can build up.

IMPORTANCE OF CLEANROOM FLOORING

Cleanrooms are categorised based on how effectively they are regulated and the amount of particles allowed per 1 m^3. The floor is essential to maintaining a cleanroom environment, because it is the primary surface on which contaminants can build up.

To ensure that the floor supports cleanroom requirements, it is critical to specify and install systems that provide the appropriate cleanability and functionality properties, as well as systems that do not introduce any contaminants into the environment.

Again, it is important to understand the specific requirements of the industry application the cleanroom is designed to support. For example, in a cleanroom for semi-conductor production, it is important to ensure that staff do not increase (or alter) the charge of the product they are handling. This can be achieved by installing flooring with electro static discharge (ESD) properties. Static (charge / rate) in a cleanroom needs to be managed carefully as it can create ESD that can harm electronics and may also attract particulates.

A cleanroom floor in a pharmaceutical industrial application will be subject to different requirements. In this case, one of the most important requirements is to ensure the flooring will not allow the growth of bacteria and can be easily decontaminated.

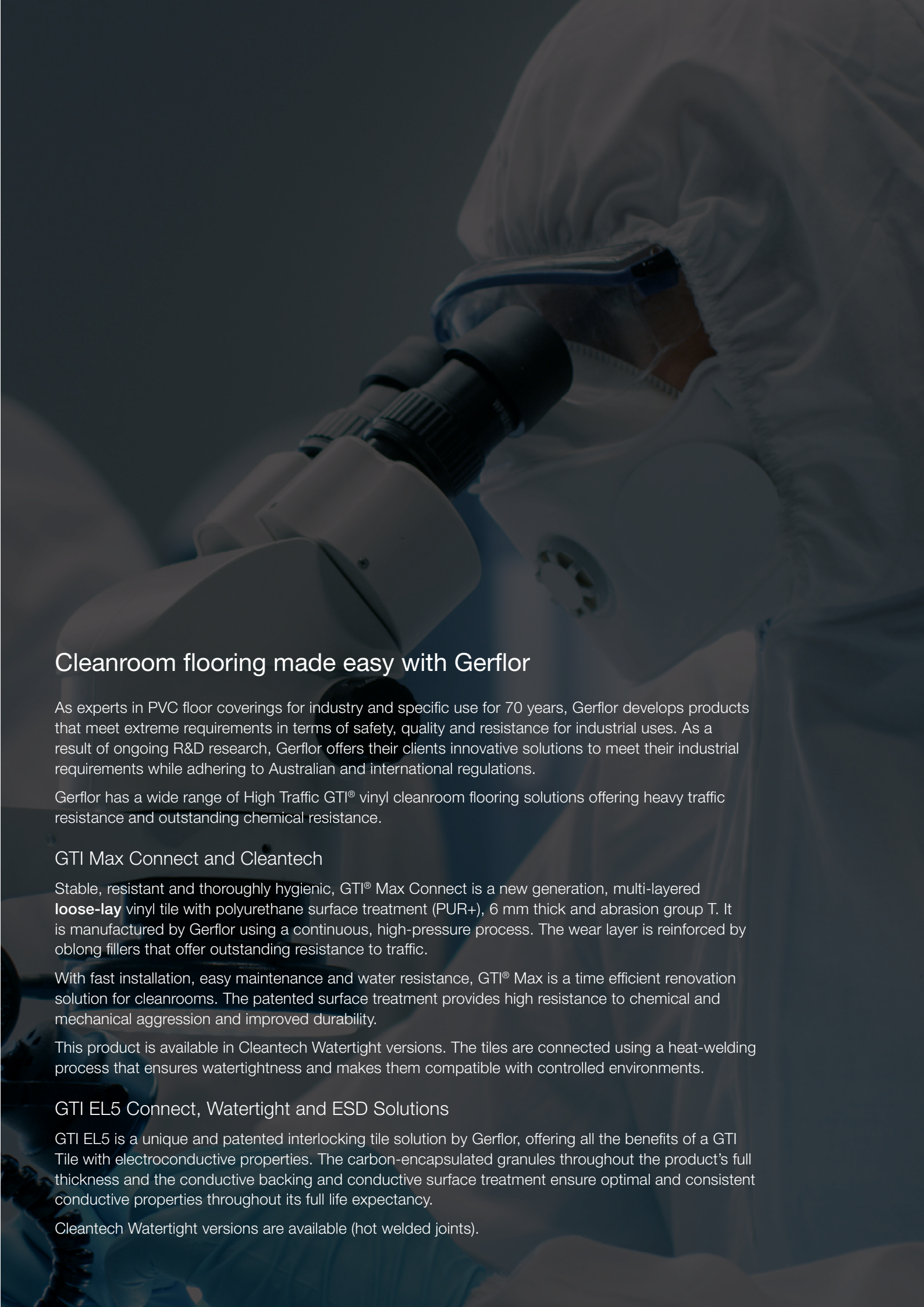
SPECIFYING CLEANROOM FLOORING MATERIALS

When specifying flooring materials, cleanroom requirements should be defined in the early stages of the project. This will include operational and maintenance requirements, expected floor traffic and wear, installation considerations and aesthetics; all these factors are necessary to meet the measures used to control particles in accordance with ultra-clean ISO standards.

Cleanroom flooring materials can vary widely based on these requirements. Maybe a floor resistant to harsh cleaning chemicals is needed, or does the floor have to eliminate constant electrical charges to prevent ESD. For convenience, we list below some of the key attributes to look for when choosing a cleanroom floor.

Key attributes

- **Cleanability.** The type of floor will determine how easy it is to clean; this includes how often it needs cleaning, the equipment needed and what types of chemicals can be used to clean. Some applications will require the use of stronger chemicals to meet cleanroom standards of cleanliness.
- **Chemical resistance.** The floor may be required to resist chemical or solvent spills. Certain flooring materials are easily damaged when exposed to common substances found in pharmaceutical and medical device cleanrooms to maintain sterility.
- **Biocontamination control.** It is important to understand how micro-organisms behave when coming into contact with the floor. A scientific assessment of the microbial behaviour on the floor's surface may be required. Certain floors may include anti-microbial additives that prevent bacterial growth on the floor.
- **Airborne particle release control.** In order to maintain an optimal level of cleanliness, cleanrooms must be free of materials that will release particles or outgas (the release of gas that was trapped in the material).
- **Temperature resistance.** Some cleanroom activities will expose floors to extreme temperatures due to processing, equipment and cleaning. In such cases, floor materials should be designed to resist extreme temperatures and extreme changes in temperature.
- **Weight, loads and intensity of traffic.** The floor should be designed to withstand the environment's intended use and traffic, including the likelihood of impacts, abrasions, chemical attacks and temperature changes. A floor that is damaged could crack and flake, providing conditions to trap particulates and bacteria. A related consideration is how easily the floor can be replaced if it is damaged.
- **ESD properties.** Specific cleanroom floors utilise elements within the flooring material to reduce static electricity and protect electrostatic-sensitive devices.
- **Fire safety.** Fire-rated cleanrooms must be constructed with floors that are designed to resist the spread of fire and provide a barrier between the cleanroom and adjacent spaces.
- **Third-party certification and quality.** Cleanroom materials should be tested and certified to ensure they are suitable for the proposed application.
- **Product ergonomics.** Comfort underfoot is an important consideration if staff are expected to work on their feet for long hours or are working in physically demanding work conditions.



Cleanroom flooring made easy with Gerflor

As experts in PVC floor coverings for industry and specific use for 70 years, Gerflor develops products that meet extreme requirements in terms of safety, quality and resistance for industrial uses. As a result of ongoing R&D research, Gerflor offers their clients innovative solutions to meet their industrial requirements while adhering to Australian and international regulations.

Gerflor has a wide range of High Traffic GTI® vinyl cleanroom flooring solutions offering heavy traffic resistance and outstanding chemical resistance.

GTI Max Connect and Cleantech

Stable, resistant and thoroughly hygienic, GTI® Max Connect is a new generation, multi-layered **loose-lay** vinyl tile with polyurethane surface treatment (PUR+), 6 mm thick and abrasion group T. It is manufactured by Gerflor using a continuous, high-pressure process. The wear layer is reinforced by oblong fillers that offer outstanding resistance to traffic.

With fast installation, easy maintenance and water resistance, GTI® Max is a time efficient renovation solution for cleanrooms. The patented surface treatment provides high resistance to chemical and mechanical aggression and improved durability.

This product is available in Cleantech Watertight versions. The tiles are connected using a heat-welding process that ensures watertightness and makes them compatible with controlled environments.

GTI EL5 Connect, Watertight and ESD Solutions

GTI EL5 is a unique and patented interlocking tile solution by Gerflor, offering all the benefits of a GTI Tile with electroconductive properties. The carbon-encapsulated granules throughout the product's full thickness and the conductive backing and conductive surface treatment ensure optimal and consistent conductive properties throughout its full life expectancy.

Cleantech Watertight versions are available (hot welded joints).

All information provided correct as of March 2024