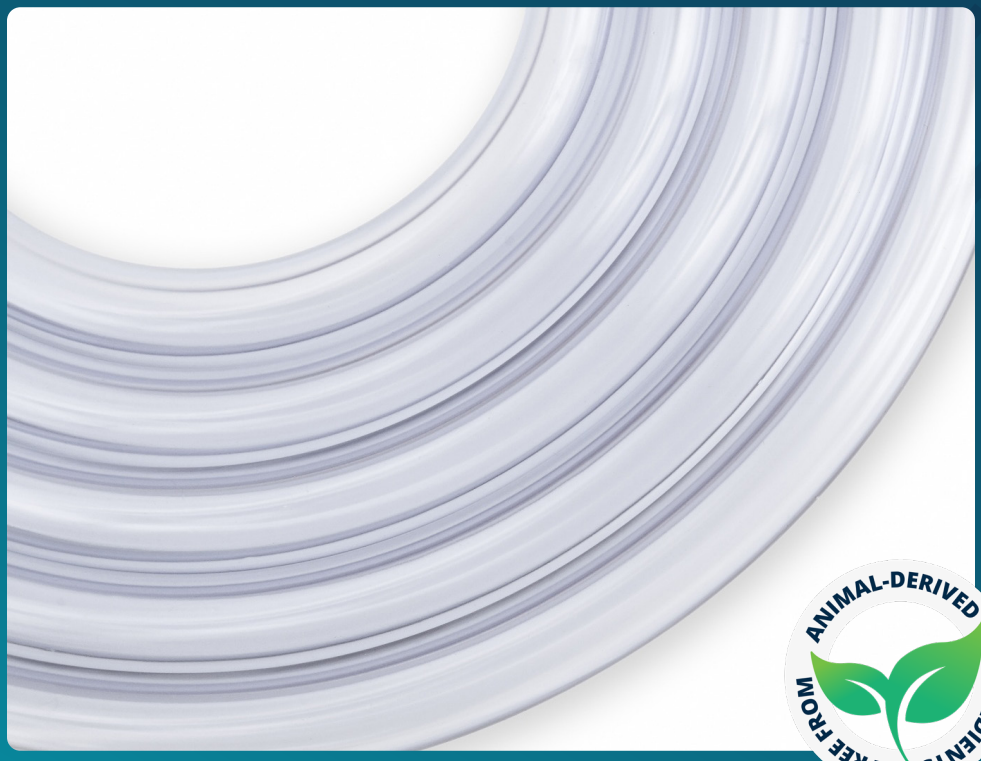
SANISURE
Solution Based Innovation

Setting the Weld Standard: Validating Cleargreen®Pure Tubing for Closed-System Bioprocessing



Executive Summary

As biopharmaceutical companies race to bring cell and gene therapies to market, the performance expectations for every component in the manufacturing process continue to climb—especially for tubing used in closed, sterile systems. Traditional PVC formulations are increasingly limited by their reliance on DEHP, lack of gamma stability, and variable weld performance. At the same time, regulators and manufacturers alike are prioritizing materials that minimize contamination risk, enable sustainability, and support aseptic integration.

SaniSure® developed Cleargreen®Pure to meet these emerging demands. This animal-derived ingredient-free, DEHP-free, and gamma-stable tubing was engineered for clean, reliable weldability and sterile bioprocessing compatibility. A newly completed comparative study (TR-1092) evaluated Cleargreen®Pure against two market-leading PVC tubing products—Tygon ND 100-65 and Raumedic MED8036—across a range of criteria, including particulate release, visual weld flash, tensile strength, and burst pressure.

The results confirm that Cleargreen®Pure meets or exceeds performance benchmarks in every category:

- Clean welds and low particulate burden, meeting USP <788> standards
- Strong mechanical performance, with weld strength and burst pressure equal to or better than traditional options
- Hybrid weld compatibility, enabling seamless use with other legacy PVC tubing
- Proven gamma stability up to 45 kGy for sterilized single-use assemblies

With demonstrated performance and a material profile aligned to modern regulatory and sustainability goals, Cleargreen®Pure offers manufacturers a drop-in replacement for conventional PVC—and a pathway to future-ready fluid management in cell and gene therapy, blood processing, and aseptic biologics production.

Introduction: The Critical Role of Tubing in Advanced Therapy Manufacturing

As the life sciences industry accelerates its pursuit of transformative treatments—including cell and gene therapies, autologous blood-based interventions, and other precision biologics—every component in the manufacturing and delivery chain must meet elevated performance, safety, and regulatory expectations. Among these, single-use tubing plays a particularly critical role.

Tubing serves as the literal and functional conduit connecting upstream and downstream operations across increasingly integrated and closed bioprocessing systems. In advanced therapy workflows, it supports sterile collection, manipulation, and reinfusion of patient-derived material. In blood collection, tubing must maintain sample integrity while enabling sterile welds and seals. In fill/finish operations, it must ensure ultra-low particulate release and withstand terminal sterilization—all without leaching harmful plasticizers or introducing variability.

While polyvinyl chloride (PVC) tubing, a historical workhorse, remains the best option for closed-loop systems for cell and gene therapy processing, legacy PVC tubing formulations are beginning to show their limitations under modern process demands. Many contain di(2-ethylhexyl) phthalate (DEHP), a plasticizer under increasing regulatory scrutiny owing to its potential to leach into drug products and potential endocrine-disrupting properties. Others lack adequate stability under gamma irradiation, limiting their ability to support pre-sterilized single-use systems. Still others fail to deliver the sterile weld compatibility needed for seamless integration into closed-loop manufacturing systems. In addition, most medical-grade PVCs are manufactured using animal tallow-based additives, making them incompatible with workflows that require materials free from animal-derived ingredients.

At the same time, the biopharma industry is undergoing a broader shift toward sustainability and safety by design. Regulators, contract manufacturers, and therapy developers alike are seeking tubing solutions that eliminate animal-derived ingredients, support circular economy principles, and meet stringent biocompatibility and extractables/leachables profiles. The goal is no longer just compliance but confidence in the cleanability, weldability, and long-term viability of every fluid contact component.

A New Standard in PVC Tubing

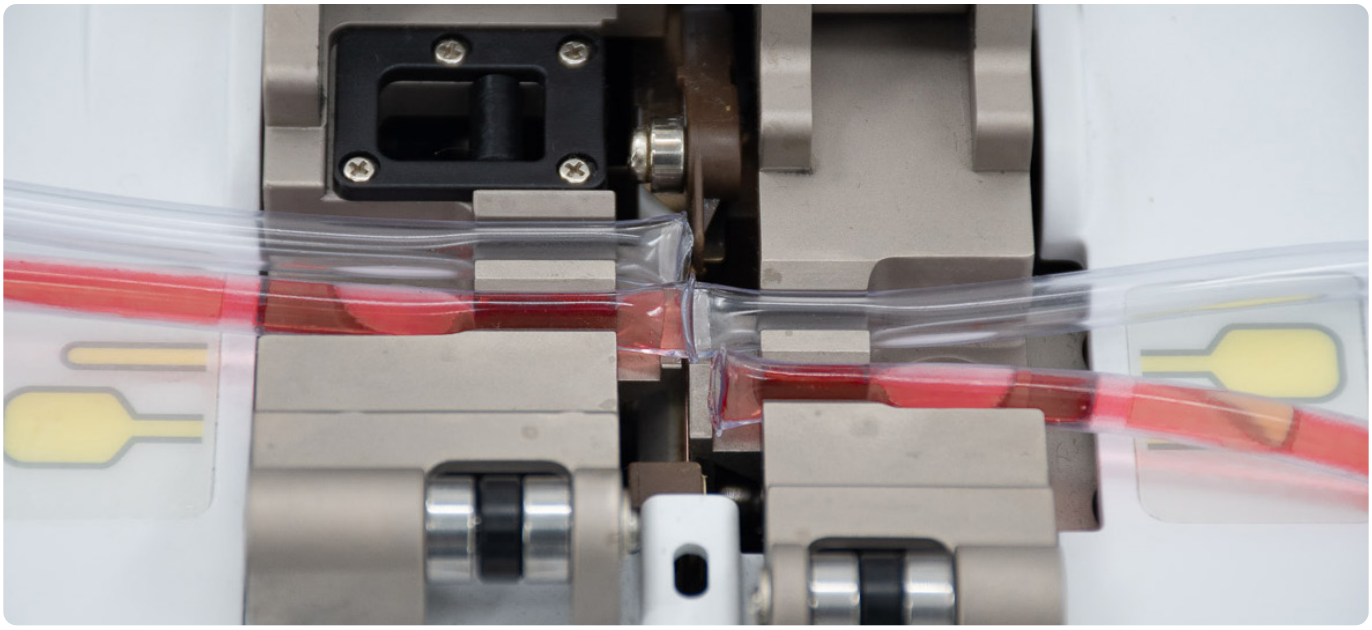
Developed by SaniSure® to address the growing limitations of conventional PVC while meeting the specialized needs of next-generation biologics, Cleargreen®Pure combines material innovation with bioprocessing practicality.

At the core of its design is a novel PVC formulation that eliminates the most concerning additives found in legacy tubing while reducing the bioburden and environmental impact associated with animal-based materials. Cleargreen®Pure is DEHP-free, removing the risks associated with phthalate leaching, which has been linked to reproductive toxicity and cellular interference. It is also bisphenol A (BPA)-free and free from animal-derived ingredients, aligning with increasing global regulatory requirements and industry preferences for materials free from both endocrine disruptors and ethically sensitive components.

This clean material profile reduces the risk of immunogenicity, pathogen transmission, and regulatory complications—especially important in cell and gene therapy (CGT), where small batch sizes, autologous materials, and vulnerable patient populations demand the highest safety standards. Combined with its low particulate shedding, Cleargreen®Pure ensures that tubing is no longer the weakest link in a high-risk workflow—but a component engineered to protect both product and patient.

At the same time, it's important to recognize why PVC remains so prevalent in CGT workflows. From blood bags to apheresis kits and leukopak systems, PVC continues to serve as the backbone of many FDA-cleared, GMP-compliant, closed single-use systems used for collection, processing, and transport. Its compatibility with anticoagulants like ACD-A, resistance to hemolysis, reliable performance in peristaltic pumping, and resilience in cold storage have all contributed to a deep regulatory legacy and widespread adoption.

Cleargreen®Pure builds on this platform, retaining the functional advantages of PVC while eliminating the additives that pose regulatory, toxicological, or sustainability challenges. It represents an evolution rather than a departure—enabling biomanufacturers to modernize tubing systems without compromising integration, performance, or process continuity.



Critically, Cleargreen®Pure has been engineered for gamma stability up to 45 kGy—an industry-leading threshold that enables terminal sterilization without compromising structural integrity or performance. This stability makes it fully compatible with gamma, E-beam, and ethylene oxide (EtO) sterilization processes, supporting a wide range of sterile manufacturing and fill/finish workflows.

The tubing is also fully compatible with aseptic welders and sealers, enabling its use in closed-system processing—a foundational requirement in cell and gene therapy and other high-risk biologic production environments. Its low particle shedding profile and validated weld performance further reinforce its readiness for sterile bioprocessing applications.

In addition to these technical features, Cleargreen® Pure reflects a broader commitment to sustainable innovation. By replacing animal-origin inputs, the tubing supports reduced greenhouse gas emissions and elimination of ethical concerns tied to animal-sourced ingredients. Its extended gamma stability and longer shelf life also contribute to a reduced waste burden—helping biopharma companies align with Environmental, Social, and Governance (ESG) goals and future sustainability mandates.

Already in use across a range of CGT and biopharma applications, Cleargreen®Pure is gaining traction as a drop-in replacement for traditional PVC tubing—without compromising on performance. Whether in media transfer sets, blood processing systems, or closed aseptic fill lines, Cleargreen®Pure provides biomanufacturers with a durable, clean, and future-ready tubing solution designed to meet the highest clinical, operational, and environmental expectations.

Study Overview: Objective, Methods, and Tubing Compared

As part of SaniSure's ongoing commitment to transparency, performance validation, and application-specific testing, a comprehensive weldability study was conducted to evaluate how Cleargreen®Pure performs against leading PVC tubing alternatives in biopharmaceutical processing environments.

The study was designed to assess weld integrity, mechanical strength, and particulate cleanliness of Cleargreen®Pure following gamma sterilization, both in self-welded configurations and in hybrid welds with other widely used tubing products. The objective was twofold:

1. Demonstrate Cleargreen®Pure's suitability for sterile, closed-system processing, where high-integrity welds are essential.
2. Benchmark its performance against legacy PVC materials to validate its use as a direct replacement in mixed-system workflows.

Test Methods and Equipment

Four key assessments were used to characterize the welded joints:

Burst Pressure Testing. Using a hydrostatic pressure rig, welded tubing samples were submerged in a water bath and pressurized until failure. This tested the ultimate pressure resistance of the welds and tubing under fluidic stress.

Tensile Strength Testing. A Houndsfield Tensometer was used to stretch welded samples until breakage, measuring maximum tensile force to assess weld durability. A nonparametric analysis with right-censored data was applied to account for occasional clamp or tubing failures not directly related to weld strength.

Particulate Release Testing (USP <788>). Ultrapure water was passed through each welded tubing sample, and released particulates were measured using a particle counter. This evaluated cleanliness at the weld site—a critical factor in maintaining fluid purity in pharmaceutical operations.

Visual Inspection of Weld Flash. Welded tubing was cut lengthwise and inspected for internal and external flash, which can affect flow dynamics and introduce particulate risk. Photographic documentation accompanied visual assessments to ensure objective comparison.

All tubing samples were gamma irradiated (25–40 kGy) before welding, reflecting real-world sterilization conditions used in manufacturing environments. The common size tested across all grades was 0.118" ID × 0.161" OD—a standard dimension widely used in blood processing applications.

Tubing Types Compared

To provide a meaningful and relevant benchmark, the study included both direct and hybrid welds among three commonly used medical-grade PVC tubing products:

- **Cleargreen®Pure.** SaniSure's animal-derived ingredient–free, DEHP-free tubing designed for biopharma and advanced therapy applications.
- **Tygon ND 100-65 (St. Gobain).** A well-established PVC-based tubing widely used in medical and biopharma processes.
- **Raumedic MED 8036.** A traditional PVC tubing product used in healthcare and single-use systems.

The study evaluated the following weld combinations:

1. Cleargreen®Pure to Cleargreen®Pure
2. Tygon to Tygon
3. Raumedic to Raumedic
4. Cleargreen®Pure to Tygon
5. Cleargreen®Pure to Raumedic

By including both like-to-like and cross-brand hybrid welds, the study provides a robust view of Cleargreen®Pure's performance under a range of real-world welding scenarios, including system upgrades or mixed-component assemblies.

Study Results and Interpretation

The weldability study confirmed that Cleargreen®Pure tubing performs at or above industry standards across all critical measures of weld quality, cleanliness, and mechanical robustness. Whether welded to itself or to other leading PVC tubing products, Cleargreen®Pure delivered reliable results that support its integration into closed bioprocessing systems for cell and gene therapy and related applications.

Particulate Testing (USP <788>)

All tubing combinations tested—including Cleargreen®Pure-to-Cleargreen®Pure and hybrid welds with Tygon and Raumedic—passed USP <788> particulate release criteria. This included compliance with the limits of ≤6,000 particles ≥10 µm and ≤600 particles ≥25 µm per 100 mL of ultrapure water.

These results validate the cleanliness of the weld interface, confirming that Cleargreen®Pure does not generate unacceptable levels of particulates during the welding process. This is especially critical for high-purity manufacturing environments, where particulate contamination can impact both process consistency and product safety.

Visual Flash Inspection

Visual inspection of the weld flash—both internal a nd external—was performed by cutting each welded sample lengthwise and documenting any excess material or deformation.

Across all five tubing combinations, weld flash was minimal and within acceptable limits. This suggests that Cleargreen®Pure welds with precision and consistency, supporting smooth fluid transfer and minimizing downstream risk of disruption or obstruction. Clean weld profiles are particularly important in sterile fill/finish processes and in tubing pathways involving pumps or sensors.

Tensile Strength Testing

Tensile testing assessed the mechanical durability of the weld joints by applying increasing force until failure. Cleargreen®Pure-to-Cleargreen®Pure welds achieved a mean maximum force of 88.0 N, outperforming Tygon (83.0 N) and approaching the performance of Raumedic (94.2 N), which had the highest average but should be interpreted cautiously, as only seven weld failures occurred in 33 tests, with the remaining 26 reflecting tubing failures not at the weld site itself.

Cleargreen®Pure also performed well in cross-material welds:

- Cleargreen®Pure-to-Raumedic: 85.0 N
- Cleargreen®Pure-to-Tygon: 77.4 N

The results confirm that Cleargreen®Pure not only forms strong welds with itself but also demonstrates excellent compatibility in hybrid welds, enabling integration into multi-vendor or phased adoption systems without compromising strength or performance.

Burst Pressure Testing

In burst pressure testing, Cleargreen®Pure-to-Cleargreen®Pure welds achieved the highest mean burst pressure at 18.1 psi, outperforming both Tygon (15.8 psi) and Raumedic (15.5 psi). Notably, in the hybrid welds (Cleargreen®Pure-to-Tygon and Cleargreen®Pure-to-Raumedic), failure often occurred in the tubing itself rather than at the weld site, indicating that the weld was stronger than the surrounding material.

This performance reinforces Cleargreen®Pure's robustness under pressure, particularly important for applications involving dynamic flow, pumping, or pressurized transfer. The fact that the tubing failed before the weld in many cases is a strong indicator of weld reliability under real-world stress conditions.

Across all four evaluation categories, Cleargreen®Pure met or exceeded the functional expectations required for high-performance tubing in advanced biopharma applications. These results underscore its ready-to-integrate capabilities, both as a drop-in replacement for legacy PVC tubing and as a key component in forward-looking single-use system designs.

Implications for Bioprocessing and Cell and Gene Applications

The findings from the weld study underscore the real-world utility of Cleargreen®Pure in demanding biopharmaceutical and cell and gene therapy manufacturing environments. As industry workflows trend toward closed-system, single-use processing, the requirements placed on tubing products—particularly in terms of weldability, cleanliness, and sterility—have grown significantly. Cleargreen®Pure has demonstrated that it not only meets these requirements but exceeds the capabilities of many legacy PVC solutions.

TABLE 1. SUMMARY OF TR-1092 WELD STUDY FINDINGS FOR CLEARGREEN®PURE AND COMPETITOR TUBING

Test	Combination	Result Summary
Particulate Release (USP <788>)	1. Cleargreen®Pure–Cleargreen®Pure 2. Tygon–Tygon 3. Raumedic–Raumedic 4. Cleargreen®Pure–Tygon 5. Cleargreen®Pure–Raumedic	All combinations passed USP <788> limits for particles ≥10 µm and ≥25 µm
Visual Flash Inspection	All five combinations	All welds exhibited limited/acceptable internal and external flash
Tensile Strength	1. Cleargreen®Pure–Cleargreen®Pure: 88.0 N (32/2) 2. Tygon–Tygon: 83.0 N (32/1) 3. Raumedic–Raumedic: 94.2 N (7/26) 4. Cleargreen®Pure–Tygon: 77.4 N (33/0) 5. Cleargreen®Pure–Raumedic: 85.0 N (24/9)	Strong performance across all welds
Burst Pressure	1. Cleargreen®Pure–Cleargreen®Pure: 18.1 psi (5/5) 2. Tygon–Tygon: 15.8 psi (7/3) 3. Raumedic–Raumedic: 15.5 psi (7/3) 4. Cleargreen®Pure–Tygon: 15.7 psi (10/0) 5. Cleargreen®Pure–Raumedic: 15.6 psi (10/0)	Cleargreen®Pure–Cleargreen®Pure had the highest mean burst pressure; all welds acceptable

NOTES:
- Figures in parentheses indicate uncensored/censored sample counts.
- "Censored" samples refer to failures occurring outside the weld (e.g., in clamps or tubing), not considered direct weld failures.
- All tubing gamma was irradiated at 25–40 kGy before testing.

Closed systems are foundational to modern aseptic manufacturing, offering reduced contamination risk and improved operational efficiency. In these systems, the ability to form strong, reliable welds—without compromising fluid integrity or requiring cumbersome workarounds—is essential. Cleargreen®Pure's high tensile strength and burst pressure performance validate its suitability for secure sterile welds, whether in cell and gene therapy workflows or fill/finish operations.

Many tubing materials degrade or become brittle when exposed to gamma irradiation, limiting their utility in pre-sterilized assemblies. Cleargreen®Pure is validated to withstand gamma doses up to 45 kGy without compromising mechanical integrity, clarity, or weld performance. This enables seamless incorporation into gamma-sterilized single-use systems, simplifying logistics and ensuring readiness for point-of-use deployment.

Process flexibility is often constrained by the interoperability of tubing components from different vendors. Cleargreen®Pure overcomes this barrier by demonstrating strong, clean welds not only with itself but also with widely used tubing such as Tygon ND 100-65 and Raumedic MG. This ensures backward compatibility in hybrid systems and allows for incremental upgrades, supporting users transitioning from legacy materials without full system overhauls.

Low particulate burden is a non-negotiable requirement for tubing in sterile drug product handling and cell processing. Cleargreen®Pure's performance in the USP <788> particulate release test confirms its ability to maintain fluid purity, making it a reliable choice for media transfer, cell washing, and closed-loop manufacturing environments where cleanroom conditions must be preserved.

Whether in upstream operations, downstream purification, patient-specific therapies, or commercial fill/finish systems, Cleargreen®Pure offers a tubing solution that aligns with the complex performance, compliance, and sustainability goals of today's biologics manufacturers. Its combination of gamma stability, aseptic weldability, low extractables, and regulatory readiness positions it as an ideal material for:

- Single-use assemblies
- Media and buffer transfer sets
- Cell manipulation, harvesting, and expansion workflows
- Blood component processing
- Final drug product filling

Conclusion: A Weld-Ready Future

In today's advanced therapies landscape—where sterility, sustainability, and system compatibility are paramount—Cleargreen®Pure delivers on every front. The study confirms that it can match or exceed the weld performance, mechanical integrity, and cleanliness of legacy PVC tubing, all while advancing the industry toward safer and more sustainable materials.

Cleargreen®Pure welds cleanly and securely, forming strong, low-flash bonds both with itself and in hybrid configurations with other leading tubing brands. It performs reliably under pressure, resists particulate shedding, and maintains its strength even after high-dose gamma sterilization—critical attributes for closed-system bioprocessing and the manufacture of high-value, patient-specific therapies.

But performance is only part of the story. Cleargreen®Pure's DEHP-free and animal-free formulation meets the growing demand for materials that minimize risk, reduce environmental impact, and align with global regulatory and ethical expectations. Combined with SaniSure's vertically integrated manufacturing platform, it offers a secure and scalable solution for companies looking to upgrade their fluid management systems without compromising process integrity.

As cell and gene therapies mature, and single-use technologies become more deeply embedded in biologics production, the demands on every component in the system will continue to grow. Cleargreen®Pure is engineered not just to keep pace—but to lead. For manufacturers seeking to strengthen their sterile processing workflows while preparing for the regulatory, clinical, and operational realities of tomorrow, Cleargreen®Pure offers a truly weld-ready future.

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