iGii

2025

GUIDE

Biocompatibility by Design

The safety profile of Gii and its implications for the future of biosensing

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Introduction

At iGii, performance has never come at the expense of responsibility. From the earliest development of Gii we understood that its success would depend as much on how safely it could be used as how well it performed.

As we push further into medical and diagnostic applications, questions around safety are an essential step towards application. What happens when Gii interfaces with the body? How does it behave in contact with skin, mucosal surfaces, or circulating blood?

This report answers those questions.

Over 18 months, a fully accredited and certified Preclinical Contract Research Organization (CRO) third party company undertook a full biological safety assessment of Gii, fulfilling ISO 10993 "Biological evaluation of medical devices" (parts 5,6,10,11 and 23) and Good Laboratory Practice. Across nine separate studies spanning systemic toxicity, skin sensitisation, implantation and extractables analysis, the results were consistent: Gii is biocompatible.

But this work goes beyond simply meeting standards. It builds a foundation of trust for clinicians, regulators and partners. This piece acts as a summary of the testing, the findings and why it matters.

A safety programme built for confidence

In parallel with performance and scale-up, iGii initiated a comprehensive biological safety testing programme to evaluate Gii under clinically relevant conditions. This included a series of in vivo and in vitro studies, conducted to the rigorous standards of ISO 10993 and OECD GLP regulations. These studies were designed to build trust with clinicians, regulators and end-users.

Over a period spanning more than 18 months, nine formal GLP-compliant studies were conducted at accredited laboratories. The testing programme included:

- Systemic Toxicity Studies (14- and 28-day exposure)
- Subcutaneous Implantation
- Dermal Irritation and Sensitisation
- In Vitro Cytotoxicity (Elution Method)
- Extractables and Leachables Analysis
- Toxicological Risk Assessment

Every study employed medical-grade protocols, validated animal models or human cell lines, and ISO-standard procedures for evaluating risk. This level of testing places iGii among a small number of nanomaterials companies with such an extensive safety profile.

A safety programme built for confidence

Across every study, the results have been consistent and conclusive; Gii is biocompatible and non-toxic.

Sub-chronic toxicity tests in rats showed no mortality, no signs of systemic toxicity and no histopathological abnormalities in major organs following intravenous and intraperitoneal administration of Gii extracts. Even over 14-day exposure periods, body weight, food intake and behaviour remained within normal ranges.

In dermal and mucosal irritation studies on rabbits, Gii extracts produced a Primary Irritation Index of 0.00, with no visible signs of erythema or oedema observed at any time point. Similarly in the Maximisation Test for skin sensitisation using guinea pigs, no allergic or sensitisation responses were reported in any test groups.

The in vitro cytotoxicity study using L-929 mouse fibroblasts found Gii to be non-cytotoxic based on ISO 10993-5 guidelines. Cells exposed to Gii extract maintained normal morphology with only slight reactivity, well below the toxicity threshold.

What about the chemistry?

Beyond biological interactions, material safety also depends on chemical cleanliness. To test for potentially harmful leachables, iGii commissioned a full Extractables and Leachables (E&L) study on Gii, carried out to ISO 10993-12 and ISO 10993-18 standards.

Multiple solvent systems were used (polar, semi-polar, non-polar) to simulate different body environments. The resulting extracts were tested using high-resolution techniques:

- ICP-MS for elemental impurities
- HS-GC-MS for volatile organics
- GC-MS for semi-volatiles
- LC-QTOF for non-volatile organics

Across all tests, the findings were reassuring. No VOCs, SVOCs or NVOCs were detected above the defined safety thresholds. A small number of elemental impurities were detected, but all were well below the Analytical Evaluation Threshold (AET) and posed no risk when scaled to clinical use.

To support these findings, a separate Toxicological Risk Assessment was conducted under ISO 10993-17. It reviewed all identified substances and calculated their tolerable intake, estimated exposure dose and margin of safety. In every case, the margin of safety exceeded the regulatory threshold by a comfortable margin, confirming that no toxicological risk exists in the intended use of Gii-based devices.

The result – a safer and smarter material platform

The meaning behind these results goes far beyond regulatory compliance. Biocompatibility is a baseline requirement for technologies that aim to integrate closely with human and animal health. By demonstrating excellent biocompatibility across routes, durations and species, Gii proves itself as a biologically reliable platform for biosensing innovation as well as high performance.

These findings confirm that Gii can be used safely in point-of-care and wearable diagnostics that come into direct contact with skin, mucosa or systemic circulation, removing key barriers for clinical adoption and accelerating product development timelines.

A new standard in material trust

Gii's unique electrically powered manufacturing process avoids the pitfalls of traditional materials where other advanced materials may carry risks related to residual solvents, catalysts or impurities from production. It contains no heavy metals, toxic chemical residues or persistent contaminants

This clean profile, coupled with its robust performance in biological environments, opens the door to safer biosensor development particularly in areas where repeat contact with the body is unavoidable.

Applications in focus

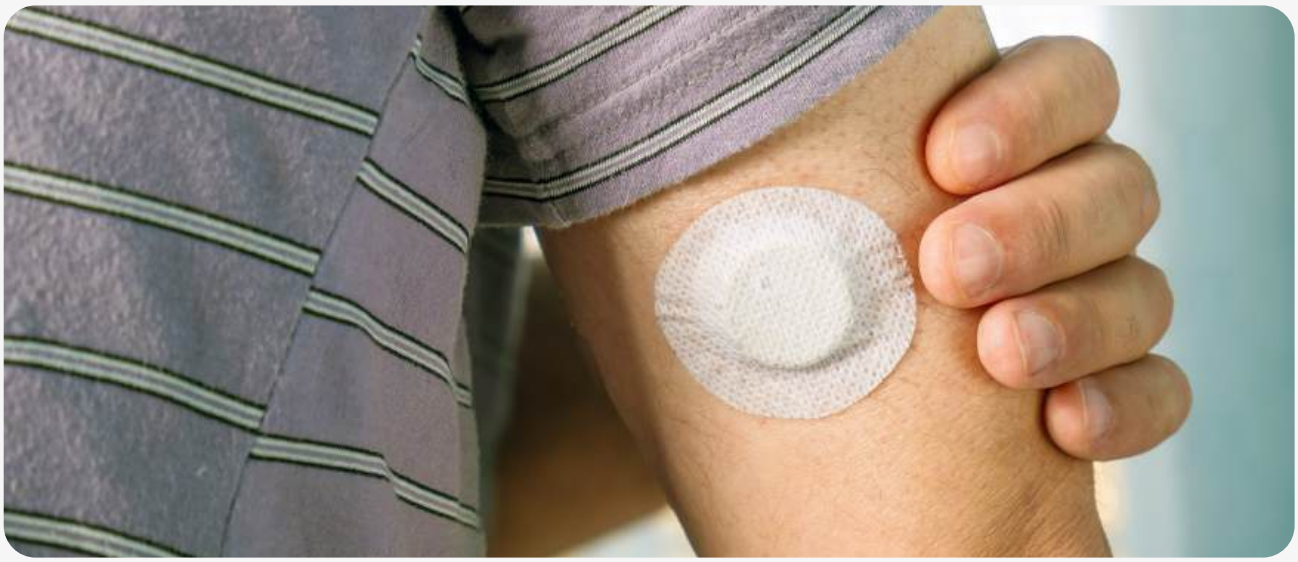
The implications of this safety data are particularly important for iGii's key market of biosensing.

From monitoring cytokines like IL-10 and cortisol in saliva, to detecting glucose or lactate in sweat, Gii's electrochemical performance has already been proven. What these biocompatibility findings now confirm is that Gii is biologically ready for use as well as technically fit for purpose.

Whether in adhesive patches for stress monitoring, subcutaneous systems for chronic care or mucosal-contact devices in veterinary diagnostics, Gii supports:

- Safe integration into living systems
- Repeat contact without cumulative risk
- Confidence in regulatory approval pathways

Simply put, the material works both on paper and in practice.



Biocompatibility built for generation Gii

These safety studies form part of a deliberate, rigorous programme to prove Gii's readiness in the most demanding biological settings. For medical innovators, diagnostic developers, and health-focused manufacturers, the message is clear; Gii is ready.

Ready to be trusted in contact with the body.
Ready to perform across use cases.
Ready to replace legacy materials.

As the demand grows for biosensing technologies that work in real life rather than just in labs, Gii stands as a material designed to meet that moment. Now with biocompatibility proven to be a reality, it stands at the forefront of biosensing and diagnostics.

Want to find out more?

Get in touch today

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