Your partner
in progress

Nanomaterials and nanotechnology in medical devices

Our mission

Our mission is to ensure patient safety whilst supporting timely market access to medical technology in a sustainable manner. We strive to set the global standard through conducting impartial, responsive, robust and thorough conformity assessments, evaluations and certifications that are recognized and trusted worldwide.

Overview

Nanomaterials are found throughout the medical devices industry. They can exhibit enhanced mechanical, biological and chemical properties; they can be present in synthetic bone grafts, wound dressings, dental composites and devices involving nanotechnology-based coatings. Manufacturers need to consider how the use of nanomaterials impacts the device design, risk, biocompatibility, toxicity, and the other chemical, physical and biological properties of the device.

As a full scope Notified Body and UK Approved Body, our team of experts have broad experience in nanotechnology applied to medical devices, particularly in orthopaedic and dental devices, active implantable devices and wound care.

Devices containing nanomaterials

Nanomaterials are defined by **Recommendation 2011/696/EU** as unbound or aggregate particles where at least half of the particles have external dimensions of 1-100nm. The Medical Device Regulation (MDR), includes specific classification rules for devices incorporating or consisting of nanomaterials based on exposure potential. This risk-based approach ensures appropriate scrutiny of nanomaterials, based on current uncertainties over their clinical, biological, and toxicological risk.

It is important that manufacturers identify the use of nanomaterials in their devices to ensure that they meet the requirements of the new Regulations. There are currently no specific EU harmonized standards on nanomaterials in medical devices, but there are several general ISO standards on nanotechnology and toxicology of nanomaterials and a Technical Report with guidance on the biological evaluation of medical devices containing or generating nanomaterials (associated with the ISO 10993 series). Manufacturers should refer to the state of the art **SCENIHR guidance** for evaluating potential health effects of nanomaterials used in medical devices. There are currently no specific EU harmonized standards on nanomaterials in medical devices.

Consult the **related Standards**.

Why choose BSI for certification?

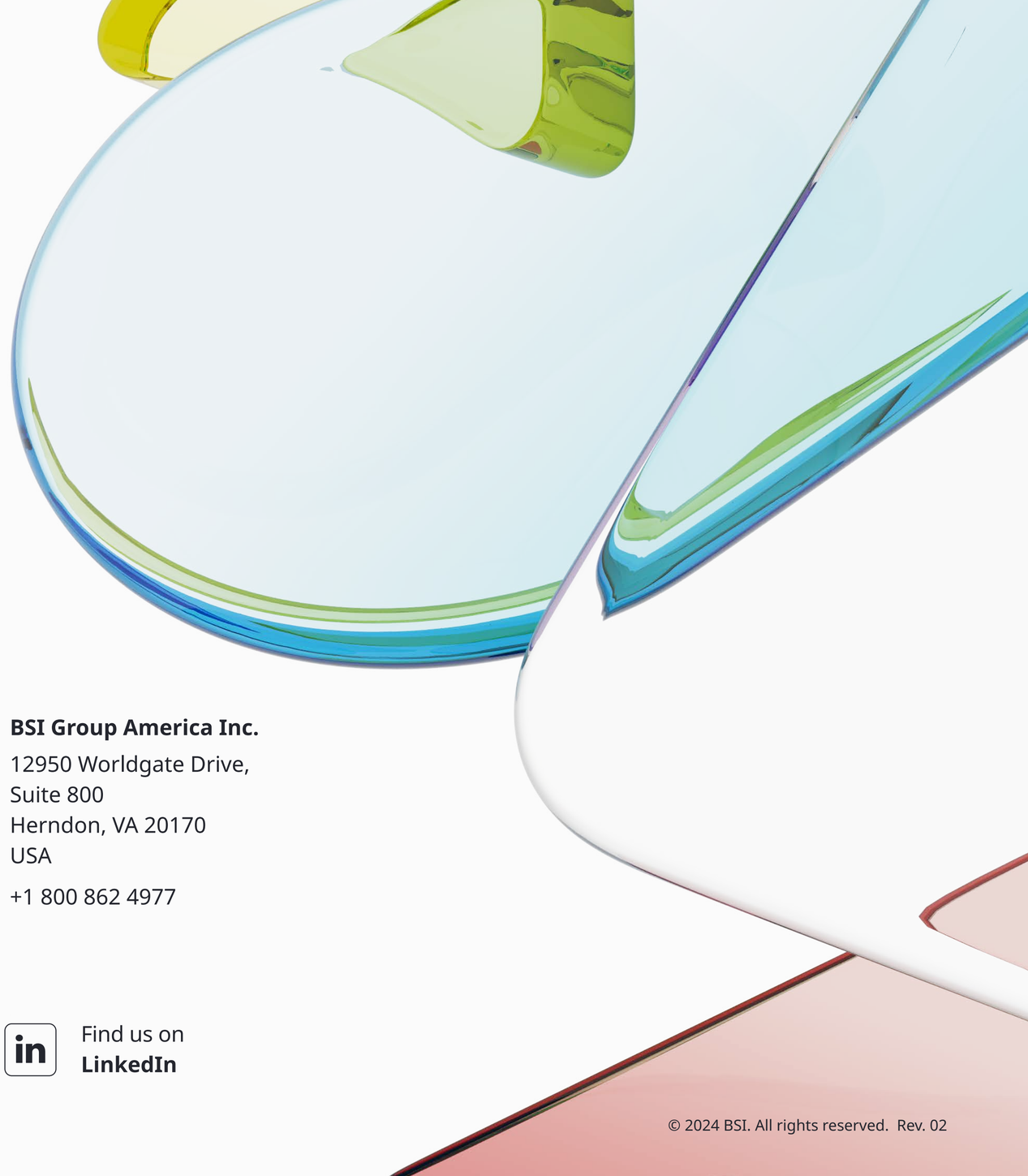
The BSI Medical Devices team has a wealth of experience with all kinds of medical technologies. Our dedicated experts are knowledgeable about specific device technologies and have experience in device design and manufacturing. This allows our team to provide a rigorous, holistic review of your medical device.

Talk to BSI today,
and start your journey

Get in touch

Whether you are starting the certification process, looking to transfer or need to discuss your options, we can guide you through the process.

Request a quote



BSI Assurance UK Ltd (0086)
Kitemark Court,
Davy Avenue, Knowlhill,
Milton Keynes, MK5 8PP
United Kingdom

+44 345 080 9000

BSI Group The Netherlands B.V. (2797)
Say Building,
John M. Keynesplein 9
1066 EP Amsterdam
The Netherlands

+31 20 346 0780

BSI Group America Inc.
12950 Worldgate Drive,
Suite 800
Herndon, VA 20170
USA

+1 800 862 4977

Find our services at
bsigroup.com/medical

Email us at
medicaldevices@bsigroup.com

Find us on
LinkedIn