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Medical Devices Certification Market Access

A country guide to medical devices certification services BSI offers to manufacturers around the globe

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Market access in Europe

European Medical Device Regulation and In Vitro Diagnostic Regulation

In Europe, medical devices and IVDs are regulated respectively by:

- **The Medical Device Regulation (MDR) (EU) 2017/745**
- **The In Vitro Diagnostic Regulation (IVDR) (EU) 2017/746**

The MDR replaced the Medical Devices Directive (93/42/EEC) and the Active Implantable Medical Devices Directive (90/385/EEC). The IVDR replaced the IVD Directive (98/79/EC).

It is manufacturers responsibility to ensure that the device complies with the General Safety and Performance Requirements of the relevant EU legislation. Full compliance of a device to harmonised standards provides “presumption of conformity” with the regulations’ Requirements. The use of harmonised standards remains voluntary as manufacturers may decide to choose other ways to fulfil the requirements.

A medical device can only be sold in Europe with a CE mark (exceptions apply for some devices such as custom-made medical devices). By placing the CE mark on a product, the manufacturer declares that it complies with all applicable European Directives and Regulations.

As a leading Notified Body for medical devices and in-vitro diagnostic medical devices, BSI The Netherlands B. V. (2797) issues CE certificates for MDR and IVDR, when required by the legislation. Class I medical devices that are non-sterile, non-reusable or with no measuring function, do not require a certificate from a Notified Body. The same applies for Class A non-sterile IVDs.

For more information visit our **MDR** and **IVDR** dedicated webpages. The European Commission also provides a **dedicated section to the Regulations**.

Why choose BSI for market access in Europe?

BSI employs more than 5000 people supported by 12,000 industry experts in more than 193 countries. Our collaborators are experienced professionals in all aspects of the product lifecycle, including research and development, manufacturing, and quality assurance. We offer specialized in-house expertise in areas ranging from sterilization processes, and animal tissue utilization to combination medical device products. Our core competencies and unique skills are calibrated to handle our customer’s extensive portfolio of medical technologies.

Market access in the United Kingdom

UK legislation and Medicines and Healthcare products Regulatory Agency (MHRA)

The Medicines and Healthcare products Regulatory Agency (**MHRA**) is responsible for regulating the UK medical devices market. In UK, medical devices and IVDs are regulated by the **Medical Devices Regulations 2002** (SI No 618, as amended) (UK MDR 2002). UK MDR 2002 replaced the Medical Devices Directive (MDD), the Active Implantable Medical Devices Directive (AIMDD) and the In Vitro Diagnostic Directive (IVDD). The UK MDR 2002 covers these directives as follow:

- Part II – General Medical Devices
- Part III – Active Implantable Medical Devices
- Part IV – In Vitro Diagnostic Medical Devices

Based on **MHRA acceptance of (EU) 2023/607**, UK government applied transitional arrangements to extend the acceptance of CE marked medical devices on the Great Britain market.

The MHRA also designates UK Approved Bodies to conduct conformity assessments against the relevant requirements for the purpose of the UKCA marking. Demonstrating compliance to the UK medical device legislation and applying the UKCA mark (with exceptions for some devices such as custom-made medical devices) allows a manufacturer to place a device on the Great Britain market. To understand which requirements you need to meet, you must classify the device and identify the appropriate conformity assessment route for your product. According to the UK legislation, the involvement of an Approved Body is required for all risk classes, except for Class I non-sterile and without measuring function devices and for self-declared general IVDs.

BSI Assurance UK Ltd (0086) is a leading full scope Approved Body under the UK legislation. We review medical devices and IVDs to ensure conformity against UK legislation through a range of flexible certification services providing you with efficient pathways to bring your product to market.

For more information, visit our **UKCA dedicated webpage** and additional resources:

- **UKCA Timeline**
- **UKCA marking with BSI**
- **UKCA RoadMap**
- **UKCA FAQs**
- **MHRA Guidance**

Market access in the United States

Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), CMDR and ISO 13485 Quality Management System

The United States (US) Food and Drug Administration (FDA) role is to protect public health by allowing only safe and effective products to enter the market, and by monitoring products for continued safety after they are in use.

The **FDA Center for Devices and Radiological Health (CDRH)** is responsible for regulating companies that manufacture, repackage, re-label and/or import medical devices sold in the US.

For additional information on medical devices processes in the US please consult **FDA Medical Devices.**

The United States and the Medical Device Single Audit Program (MDSAP)

The Medical Device Single Audit Program (MDSAP) allows manufacturers to undergo a single audit to meet the QMS/GMP requirements of multiple Regulatory Authorities (RAs). BSI is a Recognized Auditing Organization in the Medical Device Single Audit Program (MDSAP) which supports the registration of medical device products and manufacturing facilities in the MDSAP Member countries of Australia, Brazil, Canada, Japan and the United States. A BSI MDSAP audit can also be combined with assessment for MDR, IVDR, UK MDR, ISO 9001 and ISO 13485.

The **US FDA will accept the MDSAP audit reports as a substitute for FDA routine inspections**. Inspections conducted “For Cause” or “Compliance Follow-up” by FDA will not be affected by this program. Moreover, the MDSAP does not apply to any necessary pre-approval or post approval inspections for Premarket Approval (PMA) applications or to decisions under section 513(f)(5) of the Act (21 U.S.C. 360c(f)(5)) concerning the classification of a device.

Market access in Australia

Australian Medical Device Regulations

All medical devices and in vitro diagnostic medical devices are regulated by the **Therapeutic Goods Administration** (TGA). The TGA requires that all devices undergo the registration process to gain market access in Australia, timelines for processing are dependant on the device classification. For non Australian organisations, a legally appointed Australian Sponsor is required who can aid with the device registration activities.

Device classification in Australia is per Schedule 2 of the Therapeutic Goods (Medical Devices) Regulations 2002 for medical devices and in schedule 2A of the Therapeutic Goods (Medical Devices) Regulations 2002 for In Vitro diagnostic medical devices. Within schedule 2 there are 28 rules that aid organisations to classify their device(s) and within schedule 2a there are 8 rules which help classify IVD devices. Device classifications are Classes I, Im, Ir, IIa, IIb and III and IVD are Classes 1,2,3 and 4.

Quality Management system certification is a requirement for Class I (Im, Ir), Class IIa, IIb and Class III devices (including IVD device classifications of Class 2, 3 and 4); however if an MDSAP report exists, this can also be acceptable by the TGA.

Australia and the Medical Device Single Audit Program

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The TGA have participated in the MDSAP program since 2012 when it first began as a work item with the IMDRF. As part of the evidence that sponsors and manufacturers need to comply with the TGA will review the MDSAP audit reports and certificates as part of the evidence pack. Whilst the TGA have specified that they will not typically audit manufacturers who have been audited under the MDSAP programme, they have reserved the right to do that if deemed necessary.

Market access in Brazil

Brazilian Medical Device Regulations

Brazil is one of the most interesting new export markets for medical device manufacturers in North America, Europe and Asia. As one the BRIC economies (Brazil, Russia, India, South Africa, Egypt, Ethiopia, Iran, United Arab Emirates and China) it represents significant market growth opportunities.

All medical devices in Brazil are regulated by the **Brazilian Health Surveillance Agency** (ANVISA). ANVISA requires that all devices must complete a device registration process. Non-Brazilian manufacturers need a local Brazilian Registration Holder (BRH) based in Brazil to submit technical files to ANVISA.

The Brazilian Regulation uses a risk-based classification system to classify devices into one of four groups: Class I (low risk) to Class IV (high risk). In addition, all your manufacturing locations must comply with Brazilian GMP requirements for medical devices (RESOLUÇÃO DA DIRETORIA COLEGIADA - RDC N°16, Brazilian regulations similar to ISO 13485). For manufacturers with a QMS audited by an Auditing Organization and issued a Medical Device Single Audit Program (MDSAP) certificate, the on-site inspection is waived.

Brazil and the Medical Device Single Audit Program

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ANVISA utilizes the outcomes of the program, including the reports, to constitute an important input on ANVISA's pre-market and post market assessment procedures. It provides, when applicable, key information that is expected to support regulatory technical evaluation on these issues.

Market access in Canada

Canadian Medical Device Regulations and ISO 13485

Health Canada requires manufacturers who wish to sell Class II, III, and IV medical devices into Canada to provide an **ISO 13485** quality system certificate, as evidence of compliance to the Canadian Medical Device Regulations (CMDR).

This certificate can only be issued by an **MDSAP Auditing Organization (AO)** such as BSI.

CMDR and ISO 13485 Quality Management System

The Canadian Medical Device Regulations (CMDR), which took effect on January 1, 2003, is the regulation that must be followed in order for manufacturers to place medical devices on the market in Canada. For manufacturers of Class II, III, and IV medical devices, an ISO 13485 Quality Management System is required.

Class II devices require the manufacturer's declaration of device safety and effectiveness, whereas Class III and IV devices present a greater potential risk and are subject to in-depth scrutiny. For additional information consult **Health Canada Guidance on device classification**.

For additional information consult:

- **Health Canada Medical Devices Guidance**
- **Health Canada Recognized Registrars**

Canada and the Medical Device Single Audit Program

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Any manufacturer wishing to obtain a Medical Device License to sell devices into Canada will need to be certified under MDSAP.

Market access in Japan

Japanese Pharmaceutical and Medical Device Act Regulation

The distribution of medical devices in Japan is regulated in accordance with the Pharmaceutical and Medical Device Act (PMD Act) Regulation by the Ministry of Health, Labour and Welfare (MHLW).

Pharmaceutical and Medical Devices Agency (PMDA) review process

Under PMD Act, the **Pharmaceutical and Medical Devices Agency (PMDA)** review process depends on the classification of the medical device, which is generally in line with the principles outlined by the **International Medical Device Regulators Forum**:

Class I General Medical Devices: Pre-Market Submission (Todokede)

- Devices of low risk to the human body
- Approval of the product is not required, but marketing notification (Todokede) to PMDA is necessary

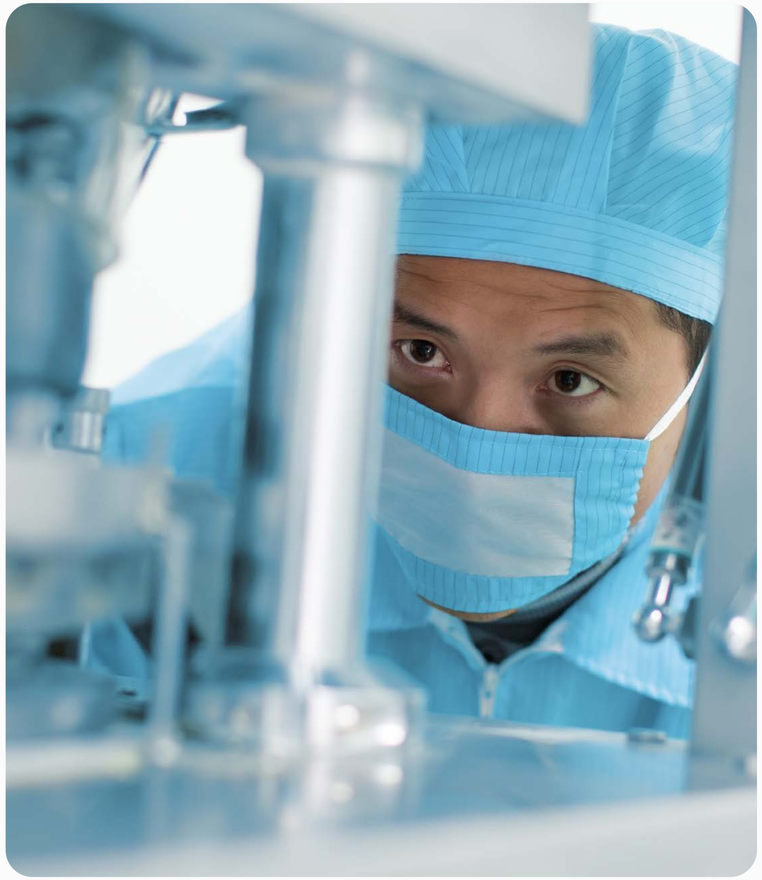
Class II and Class III (partially) Controlled Medical Devices: Pre-Market Certification (Ninsho)

- Low risk to the human body
- Most of these devices for which certification standards have been established by MHLW, are eligible for third-party review and certification by a Registered Certification Body, such as BSI. Those devices for which no applicable certification standard has been established must be submitted to PMDA for approval (Shonin) by MHLW

Class III and IV Specially Controlled Medical Devices: Pre-Market Approval (Shonin)

- Medium risk to human body, high risk to human body, highly invasive to patients
- MHLW approval (shonin) is required for Class III and IV devices, based on approval standards for devices for which such standards have been established, or based on review guidelines

For additional information consult also Pharmaceuticals and Medical Devices Agency website.



Japan and the Medical Device Single Audit Program

The Medical Device Single Audit Program (MDSAP) allows manufacturers to undergo a single audit to meet the QMS/GMP requirements of multiple Regulatory Authorities (RAs). BSI is a Recognized Auditing Organization in the Medical Device Single Audit Program (MDSAP) which supports the registration of medical device products and manufacturing facilities in the MDSAP Member countries of Australia, Brazil, Canada, Japan and the United States. A BSI MDSAP audit can also be combined with assessment for MDR, IVDR, UK MDR , ISO 9001 and ISO 13485.

The Ministry of Health, Labour and Welfare (MHLW) and the **Pharmaceutical and Medical Devices Agency (PMDA)** will utilize these audit reports in both pre-market and periodical post-market audit under regulations in Japan.

Why choose BSI for market access in Japan?

We are one of a few Certification Bodies (RCB) that is authorized to conduct certifications by the MHLW for all types of Class II and Class III medical devices and in-vitro diagnostic reagents. We also provide several solutions for our global customers wishing to access the Japanese market, including MDSAP auditing as a recognized Auditing Organization (AO). So as your company grows and expands sales into overseas markets, we can support your regulatory needs, allowing you to meet the increasingly complex regulatory schemes and certifications.

Market access in Malaysia

Malaysian Medical Devices Regulations

The regulation of medical devices in Malaysia is carried out by the regulatory authority called **Medical Device Authority (MDA)**, of the Ministry of Health. Parts of the execution and surveillance of the Regulation by the Regulatory Authority may be delegated to a **Conformity Assessment Body (CAB)**. BSI has been approved as a CAB to provide both Good Distribution Practices for Medical Devices (GDPMD) and Product Verification (Abridged process). The CABs need to be designated and operate within surveillance of the regulatory authority.

The Malaysian Medical Device Act 2012 (Act 737) was fully enforced on July 1, 2013. Whilst the medical devices industry in Malaysia has enjoyed consistent growth over the past few years, many in the industry recognize that the Medical Device Act 2012 (Act 737) has further improved the export quality of medical devices from Malaysia thus driving further growth across the country and region. This means that all medical device manufacturers in Malaysia now have to comply with the Regulation by registering their medical devices and obtaining an establishment license to import and distribute medical devices locally in Malaysia.

Malaysian medical devices classification and registration

Medical devices are registered and categorised by class or risk as shown below, including some examples of each class:

A - Low risk: surgical instruments, tongue depressor, liquid in glass thermometer, examination light, simple wound dressing, oxygen mask, stethoscopes and walking aids.

B - Low to moderate risk: hypodermic needles, suction equipment, anaesthetic breathing circuits, aspirator, external bone growth simulators, hearing aids, hydrogel dressings, patient controlled pain relief, phototherapy unit and X-ray films.

C - Moderate to high risk: lung ventilator, orthopaedic implants, baby incubator, blood oxygenator, blood bags, deep wound dressing, defibrillator, radiological therapy equipment and ventilators

D - High risk: pacemakers & their leads, implantable defibrillators, implantable infusion pumps, heart valves, neurological catheters, vascular prostheses & stents.

Note: as of April 2016, Class A devices are exempt from conformity assessment in Malaysia. However, they must be registered with the MDA, and must continue to meet several other requirements, including post-market obligations.

Market Access in Malaysia

Manufacturers wishing to apply Market Access procedures for Malaysia can reference the requirements outlined on the **MDA website**.

Manufacturers can utilize their RvA and/or UKAS ISO 13485 certificates as part of the submission pack for Market Access.

Why choose BSI for market access in Malaysia?

BSI has been approved and registered as a CAB by the MDA. In this role, BSI is responsible for independently assessing medical device manufacturers, importers and distributors to ensure that they comply with the requirements set out in the Medical Devices Act 2012 (Act 737).

BSI is currently registered to assess Quality Management Systems against ISO 13485, Good Distribution Practice for Medical Devices and Product Verification utilizing an abridged process.

Market access in Singapore

The Regulation of medical devices in Singapore is conducted by the Health Science Authority who regulate a large portfolio of products, including medical devices. Medical devices are regulated in Singapore under the **Health products Act and the Health Product (Medical Devices) Regulations 2010.**

Manufacturers are required to obtain a dealer license before they can manufacture, import, or supply medical devices in Singapore. All devices also require registration with the HSA before they can be supplied except for Class A low risk medical devices.

Devices are classified as:

Class A – Low risk: wheelchair or tongue depressor

Class B – Low to moderate risk: hypodermic needles or suction equipment

Class C – Moderate to high risk: ventilators or bone fixation plates

Class D – High risk: heart valves or implantable defibrillator

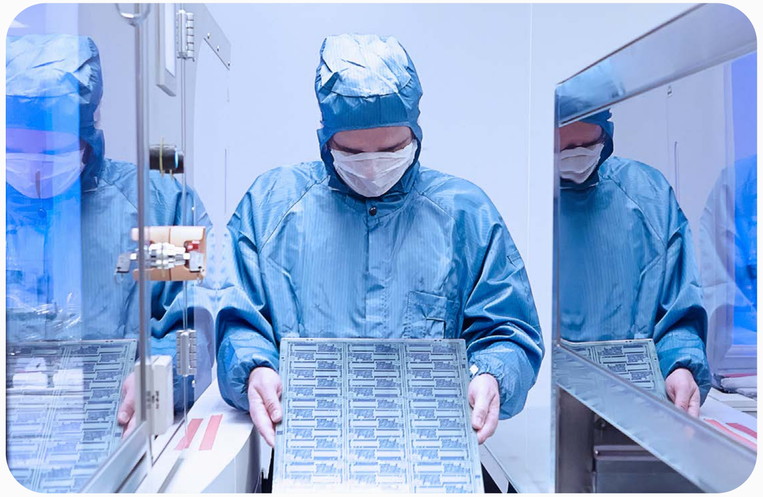
As part of market access requirements, a medical device dealer license must be obtained. There are different options:

Manufacturers License – allows a manufacturer to make, fabricate, produce, or process a medical device and also package and label a medical device before it is supplied.*

Wholesalers License – allows the wholesaler to supply a medical device by wholesale, supply a medical device to a party for re-supply or supply a medical device as a commercial sample.**

Importer License – allows the importer to import medical devices in Singapore.**

Effective from January 1, 2025, dealers who use ISO 13485 certificates as a prerequisite for their medical device dealer's license application must ensure their certificate is issued by an SAC-accredited certification body. Importers and wholesalers, depending on their activities, have the option to continue utilizing SAC-accredited GDPMDS certification based on the SS620 standard for the licensing application or to leverage their ISO13485 QMS by obtaining an SAC accredited ISO13485 certificate.



BSI is accredited by SAC under SS620 and ISO 13485. As we gear up for the full implementation of SAC ISO 13485, we encourage you to contact us and explore how we can assist you in Singapore.

* By January 1st, 2025, all manufacturer licenses will require to have been supported by an SAC ISO 13485 or MDSAP certificate.

** This license application/renewal requires either GDPMDS or SAC accredited ISO13485 or MDSAP certificate.

Market access in Taiwan

The Taiwan Technical Cooperation Programme- TCPIII

The objective of the Technical Cooperation Programme is to reduce the potential duplication of auditing efforts of EU manufacturers by TFDA-AAOs and Taiwan manufacturers by Notified Bodies resulting in reduced costs for manufacturers and may boost speed to market.

Under conditions, TCP-III enables QMS audit reports and QMS certificates to be exchanged between TFDA-recognised Notified Body partners and TFDA-Authorised Auditing Organisations (AAOs). These documents can support product applications by manufacturers based in the EU, Switzerland, or Lichtenstein, and support EN ISO 13485 applications by manufacturers based in Taiwan.

Benefit to manufacturers in the EU, Switzerland, and Lichtenstein

TCP-III enables manufacturers in the EU, Switzerland, or Lichtenstein to use an abbreviated submission route under certain conditions when applying for product registration in Taiwan. Manufacturers must have completed a QMS audit covering the requirements of EN ISO 13485 and all applicable R.O.C. QMS requirements.

A client that is signed up to the TCP-III scheme with BSI can provide documentation from BSI NL to an AAO as part of their application for product registration:

- QMS audit report covering EN ISO 13485 and all applicable R.O.C. QMS requirements
- RvA accredited EN ISO 13485 certificate
- Regulatory Letter issued by BSI as a TFDA-recognised NB partner confirming the requirements of TCP-III are met

This reduces duplication in the audit of certain elements of the Quality System Documentation (QSD) by an AAO. Audit of the QSD is only part of the overall product license application in Taiwan and additional registration requirements still apply.

Why choose BSI for market access in Taiwan?

As of 02 September 2022, BSI (NB 2797) is recognised by **Taiwan Food and Drug Administration (TFDA)** as a Notified Body partner in TCP-III. EU-based clients holding an RvA accredited EN ISO 13485 certificate can now contact BSI to apply for the Taiwan TCP-III scheme. Taiwan based manufacturers that hold also hold ISO 13485 can request an audit duration reduction from BSI with the submission of a TFDA/AAO issued QMS report that indicates the Taiwan Medical Device act as part of the audit criteria.

For additional information consult also **Taiwan Medica Device Database**.

Recognized QMS Certificates

Market Access in Egypt

Under Egyptian Decree 415, Conformity Assessment Bodies operating in Egypt are required to be registered with the Egyptian Organisation for Standards for recognition of the accredited ISO 13485 certificates. BSI completes an annual registration with the EOS for recognition of our UKAS accredited ISO 13485 certificates. This means that manufacturers wishing to enter the Egyptian market, can utilize their UKAS accredited ISO 13485 certificates as part of market access requirements.

Market Access in South Africa

Under Announcement MD032 issued by SAHPRA, in August 2022, which requires Conformity Assessment Bodies, operating in South Africa are required to be registered with the **South African Health Products Regulatory Authority** (SAHPRA). BSI has registered with SAPHRA in recognition of both our RvA and UKAS accredited ISO 13485 certificates. This means that manufacturers wishing to enter the South African market, can utilize their ISO 13485, UKAS or RvA, as part of market access requirements.

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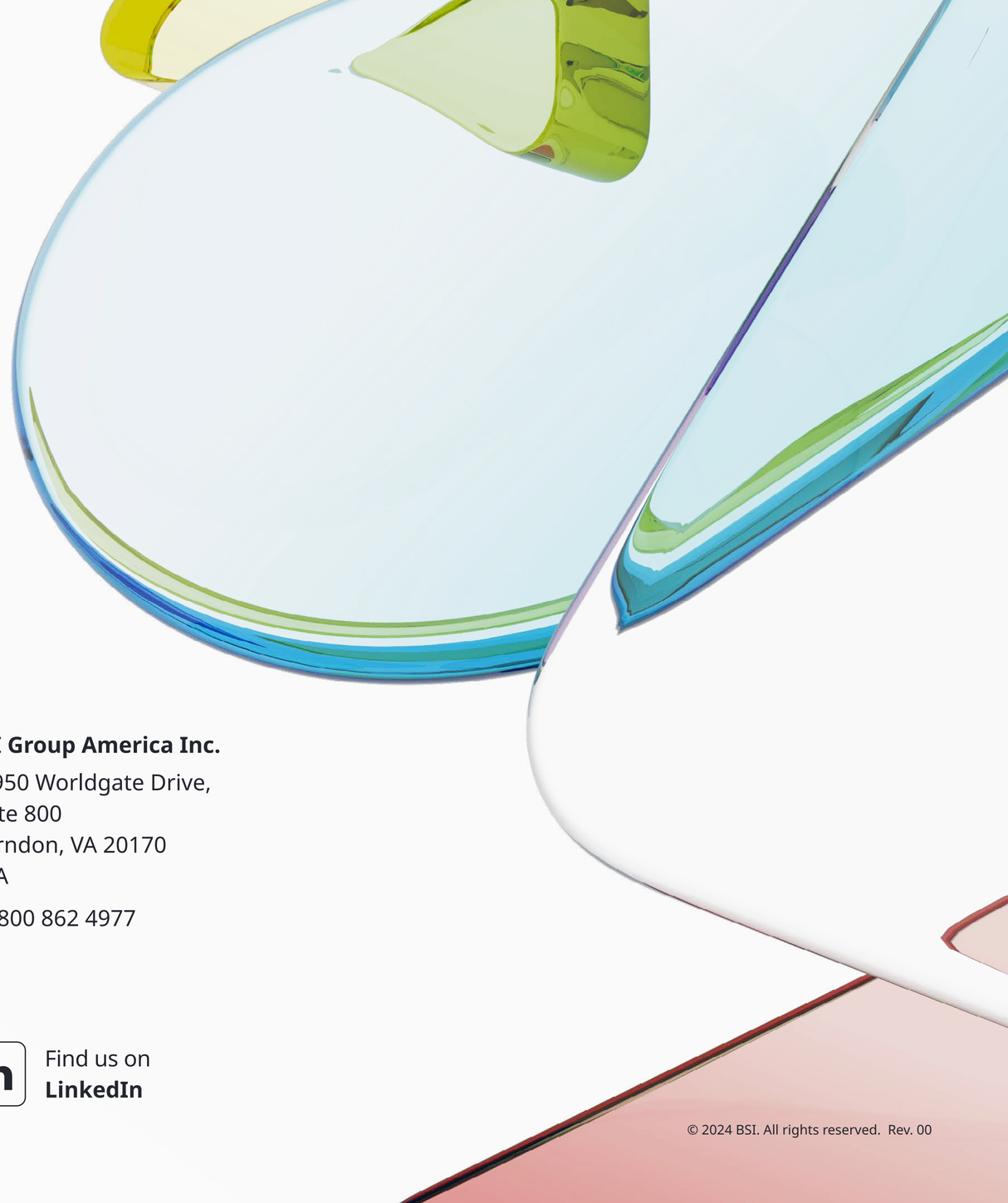

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