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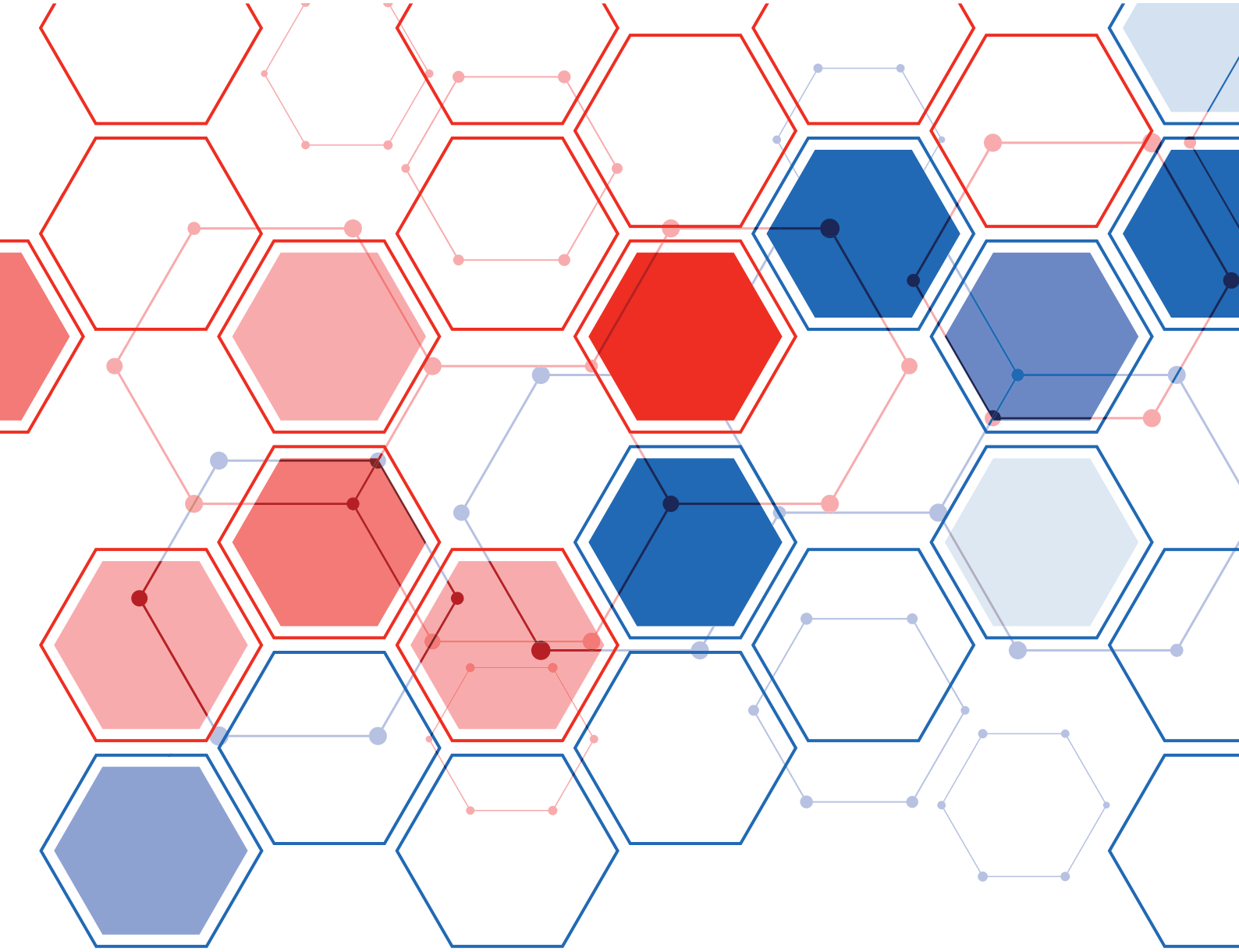


# Helping you

## to access global markets

# Welcome

## to our BSI and CSA Group Alliance

We understand how costly and time consuming it can be for medical device manufacturers to access the global market.

So, BSI and CSA Group have teamed up so we can provide medical device manufacturers with access to global markets to get devices to patients and healthcare professionals quickly.

The BSI and CSA Group alliance includes one of the world's leading medical devices Notified Bodies and testing and certification organizations working together to bring manufacturers an unrivalled mix of expertise and services.

Our mission is to help you get your products to market predictably while being fully compliant.

### Our one-stop service guides medical device manufacturers through the key stages of market access:

1. Product Testing to IEC 60601 Series of Standards for Electro-Medical Equipment and Systems
2. Product Testing to IEC 61010 Series of Standards for Laboratory, Test and Measurement Equipment
3. Public and In-house Training for CE Marking, ISO 13485, MDSAP and specialist courses
4. Quality Management System Assessment to ISO 13485, the world's most popular standard for medical devices quality management
5. Medical Device Single Audit Program (MDSAP) for access to Australia, Brazil, Canada, Japan and the United States markets
6. CE Marking to all relevant European Medical Device Directives
7. Global Market Access

**Our expert-knowledge helps you to reduce costs of delayed product launches and get your devices to patients and healthcare professionals all over the world - FASTER and more PREDICTABLY.**

## Why choose us to help you access global markets?

Our global medical technology alliance provides:

**Full Service at Every Stage**
You'll have one point of contact throughout the certification process, with experienced technical experts to guide you.

**Global Market Access**
Our worldwide office network provides expert guidance on local market needs, including the most up-to-date information on changing requirements.

**Speed to Market**
With years of experience and in-depth understanding of global requirements, we can reduce your time to market and increase your competitive advantage.

**Business Experience**
Our experience with international technical standards and regulatory requirements helps ensure your devices meet applicable safety, regulatory and quality requirements.

## About CSA Group

CSA Group is an internationally accredited provider of testing and certification services, helping manufacturers' access markets around the world. CSA Group test and certify medical products to required standards - including IEC 60601 Series of Standards for Electro-Medical Equipment and Systems and IEC 61010 Series of Standards for Laboratory, Test and Measurement Equipment - as well as offer cybersecurity assurance programs. For almost a century, CSA Group has helped clients demonstrate compliance with relevant standards for their products, helping them to reach patients and healthcare professionals around the world.

As a National Certification Body (NCB) in the IECEE CB Scheme, CSA Group is an expert source for testing & certification to IEC and ISO series of standards.

CSA Group Tests and Certifies Electro-Medical Equipment and Systems Including:

- Cardiac Defibrillators
- CT Scanners
- Electrocardiographs
- High Frequency Surgical Equipment
- Homecare Products
- Incubators
- Lung Ventilators
- Magnetic Resonance Imaging (MRI)
- Nerve and Muscle Stimulators
- Operating Tables
- Therapy Equipment
- X-ray Generators

CSA Group test and certifies laboratory, test and measurement equipment including:

- Centrifuges
- Mulitmeters
- Autoclaves
- Atomic Spectrometers
- Sterilizers
- Recording instruments
- In-Vitro Diagnostic Equipment
- Mass spectrometers

## About BSI

BSI Regulatory Services offers certification services to support your global market access goals and are:

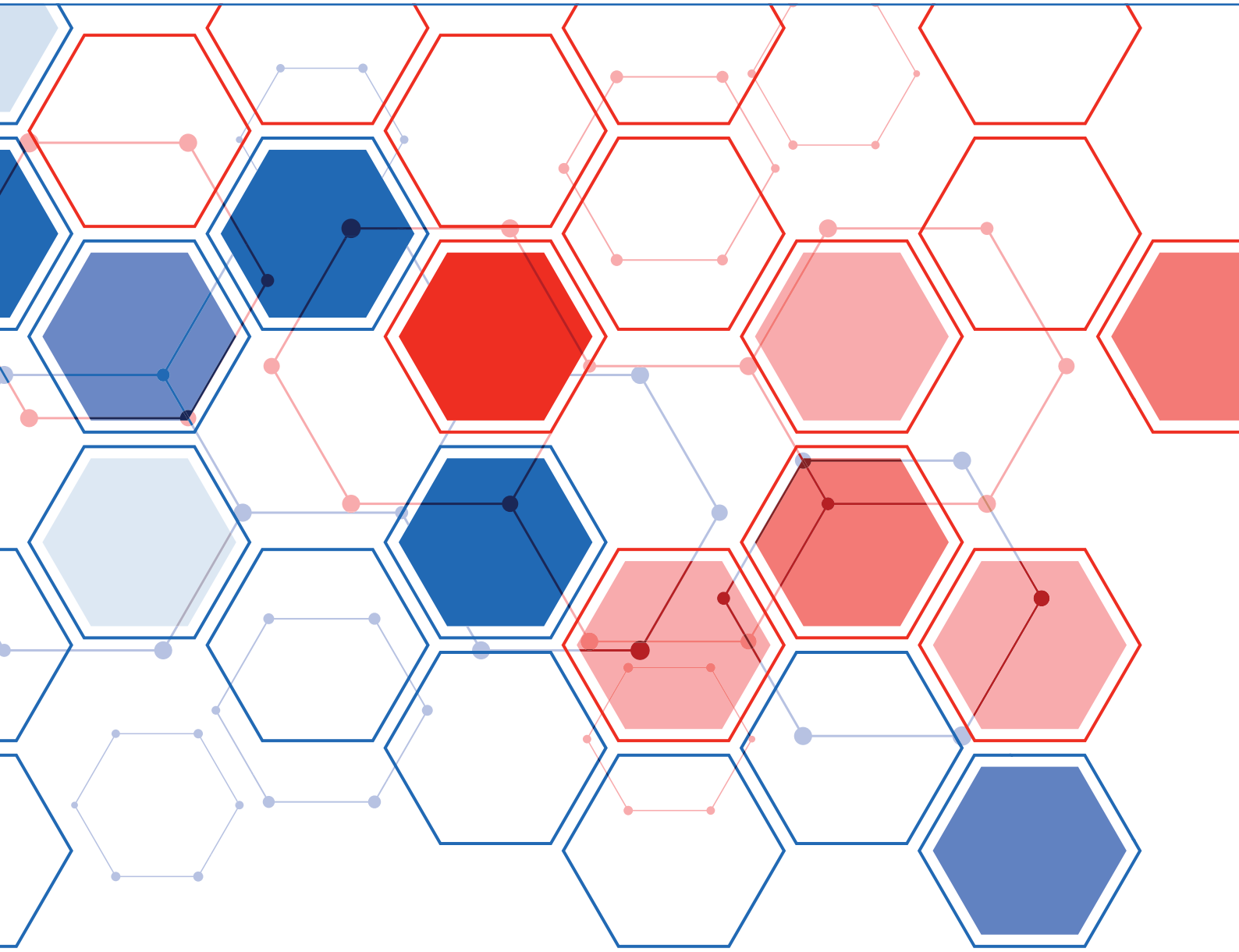
- A designated European Notified Body
- An accredited ISO 13485 Certification Body
- A recognized Auditing Organization under the Medical Device Single Audit Program, MDSAP
- A recognized Certification Body in many global markets

BSI understands the specific challenges medical device manufacturers face and the importance of bringing innovative yet safe products to global markets. Ensuring the predictability and transparency of regulatory product clearance is crucial to maintaining a competitive edge.

BSI demonstrates this commitment through:

- Over 2,050 years' medical device product and regulatory experience
- Internal Product Experts and Auditors
- Direct access to your team of technical specialists
- Our range of review services to give you flexibility

Find out more at **bsi-csa-medical-devices.com**



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