



# Unifusion<sub>B.S.C</sub>

THE UNIQUE PARTNERSHIP



# Unifusion B.S.C

A leading regulatory consulting company approved by the Saudi Food and Drug Authority (SFDA), to act as an authorized representative (AR), dealing on behalf of the medical device, IVDs, Cosmetics, Pharmaceutical manufacturers, with its headquarters in Riyadh, Kingdom of Saudi Arabia.

At Unifusion B.S.C, we turn your vision into reality with our regulatory expertise in medical devices, pharmaceuticals, and cosmetics across the MENA region, focusing on Saudi Arabia.

With over a decade of experience and strong regulatory alliances, we ensure compliance and offer training to keep your teams ahead.



## Vision

To be one of the leading global providers of innovative regulatory solutions, recognized for our commitment to excellence, integrity, and customer satisfaction.

We envision a future where our services enable businesses to effortlessly navigate regulatory landscapes, driving forward a new era of innovation and growth.

## Mission

We efficiently streamline the regulatory journey for businesses worldwide, ensuring products meet stringent standards and regulatory requirements accurately.

As trusted partners, we simplify complex regulatory requirements, mitigate risks, and empower clients to focus on innovation and growth.

Beyond compliance, we are committed to excellence, integrity, and client satisfaction, delivering tailored solutions to address specific challenges.

## ■ Regulatory Services



### Overseas Services

- **Authorized Representative (AR):**  
Acting as authorized representative, ensuring products meet the necessary legal and regulatory requirements in Saudi market.
- **Marketing Authorization:**  
Obtaining Marketing Authorization, for Medical devices, IVDs and Cosmetics from the SFDA on behalf of the manufacturer.
- **UDI Submission:**  
Assisting manufacturers with the submission of Unique Device Identification (UDI).
- **Post-Marketing Support:**  
Supporting manufacturers in post-market surveillance and vigilance reporting.

## Local Services

- **Product Classification:**  
Submitting product classification with the SFDA.
- **Local Company Registration:**  
Helping local companies obtain Medical Device National Registration (MDNR) with the SFDA.
- **Manufacturing Site Registration:**  
Assisting in registering the manufacturer's site for a Medical Device Establishment License (MDEL) with the SFDA.
- **ISO 13485 Compliance:**  
Achieving and maintaining the highest standards in medical device quality management systems.
- **Technical File Preparation:**  
Ensuring product documentation is complete, accurate, and aligned with the latest regulatory standards.



## Some of our Partners

In the world of Unifusion B.S.C, every client is a priority. We don't just offer services; we deliver tailor-made solutions that are crafted to fit the precise needs of your business. Our approach is personal, detailed, and centered

**mindray**

**UNITED  
IMAGING**

**innoDx**  
— 万泰凯瑞 —

**WEGO**

**Haier**

**COMEN**

**BIOBASE®**

**LEPU MEDICAL**

**Wondfo**

**SHINVA**

**Autobio**

**SAIKANG / Medical**

**Medcaptain**

**WOODPECKER**

**INTCO**

**Ulike**

**XINWELL**

**DEEPLUE**

**.-MED**

**HugeMed**



# Unifusion<sub>B.S.C</sub>

THE UNIQUE PARTNERSHIP

+966 55 7696 888 | [info@unifusion-bsc.com](mailto:info@unifusion-bsc.com) | [www.unifusion-bsc.com](http://www.unifusion-bsc.com)  
3rd Floor, Building #6217, Al Olaya Street, Al Olaya District,  
Riyadh, Kingdom of Saudi Arabia