MEDPACE

MEDICAL DEVICE EUROPEAN AUTHORIZED REPRESENTATIVE SERVICES

Medpace is a scientifically-driven, global, full-service clinical research organization (CRO) with a team of professionals specifically dedicated to the design, conduct, recording and reporting of clinical investigations for medical devices and performance studies for in-vitro diagnostic products.

As part of a comprehensive service to our clients, Medpace provides European Authorized Representative services for medical device manufacturers based outside the European Union (EU).

A team of regulatory professionals from the Scientific and Strategic Development (SSD) group is committed to serving as a European Authorized Representative, liaising between our clients and all EU member states plus Iceland, Norway and Liechtenstein.

Medpace helps bring products to market safely, effectively and efficiently by providing:

- Pre-market, post-approval and post-market representation
- Preliminary support with regulatory and clinical strategies and pathways
- Advice and support in complying with existing and new regulations, standards and guidance documents
- Technical support with planning and executing a smooth transition from the Medical Device Directive (MDD) or Active Implantable Medical Device Directive (AIMDD) to the Medical Device Regulation (MDR)
- Notified Body search, selection and qualification, including transferring Notified Body

MAKING THE COMPLEX SEAMLESS™

AUTHORIZED REPRESENTATIVE SERVICES

Medpace provides Authorized Representative Services in accordance with the European Medical Device Regulation (as amended), via the Medpace Maastricht office.

Medpace Medical Device B.V. (trading as MediTech Strategic Consultants B.V.)
II Fiore building B, 3rd Floor
Avenue Ceramique 227
6221 KX Maastricht
The Netherlands
MMD-Authorized-Representative@Medpace.com

UK RESPONSIBLE PERSON SERVICES

Following the decision for the United Kingdom (UK) to leave the European Union (EU), Medpace can also provide continued market access to the UK, in accordance with the UK Medical Device Regulation (as amended), via the Medpace London office.

Medpace UK Ltd
Vintners Place
68 Upper Thames Street
London
UK
EC4V 3BJ
MMD-UK-Responsible-Person@Medpace.com

Exclusively dedicated to helping our medical device clients bring products to market safely, effectively and efficiently.

EXPERTS

Our regulatory professionals are high-caliber scientists who provide deep technical expertise. Coupled with a strong commercial awareness, we can devise the optimal regulatory strategy for your product.

EXPERIENCE

From the strategic to the operational, our regulatory professionals guide you through the regulatory maze to get your device CE marked and placed on the market as quickly and efficiently as possible, whilst enhancing the value of your products with seamless compliance.

EXECUTION

As your European Authorized Representative, Medpace Medical Device B.V.:

- Operates in accordance with the European Commission guideline for Authorized Representatives, MEDDEV 2.5/10
- Provides a point of contact for EU Competent Authorities
- Manages applicable device notifications with the Dutch National Competent Authority
- Manages in-country registration depending on distributed markets
- Verifies device classification, intended use statement and can provide equivalent device determination
- Conducts a regulatory review and appraisal of technical documentation to ensure compliance with existing and new regulations, standards and guidance
- Keeps on file a copy of your full technical documentation for inspection by EU regulators
- Provides assistance with Vigilance and Field Safety Corrective Action reporting in accordance with MEDDEV 2.12/1
- Requests Free Sale Certificates to support our clients in achieving global market access
- Participates in Notified Body meetings and Competent Authority meetings
- Provides ongoing compliance support via regulatory news and updates on the changing regulations, standards and guidance

FULL-SERVICE CLINICAL DEVELOPMENT

Medpace is a scientifically-driven, global, full-service clinical contract research organization (CRO) providing Phase I-IV clinical development services to the biotechnology, pharmaceutical and medical device industries. Medpace's mission is to accelerate the global development of safe and effective medical therapeutics through its high-science and disciplined operating approach that leverages local regulatory and deep therapeutic expertise across all major areas including oncology, cardiology, metabolic disease, endocrinology, central nervous system and anti-viral and anti-infective.

WE CAN'T SIMPLIFY CLINICAL DEVELOPMENT – BUT WE CAN EXECUTE IT SEAMLESSLY.

MAKING THE COMPLEX SEAMLESS™