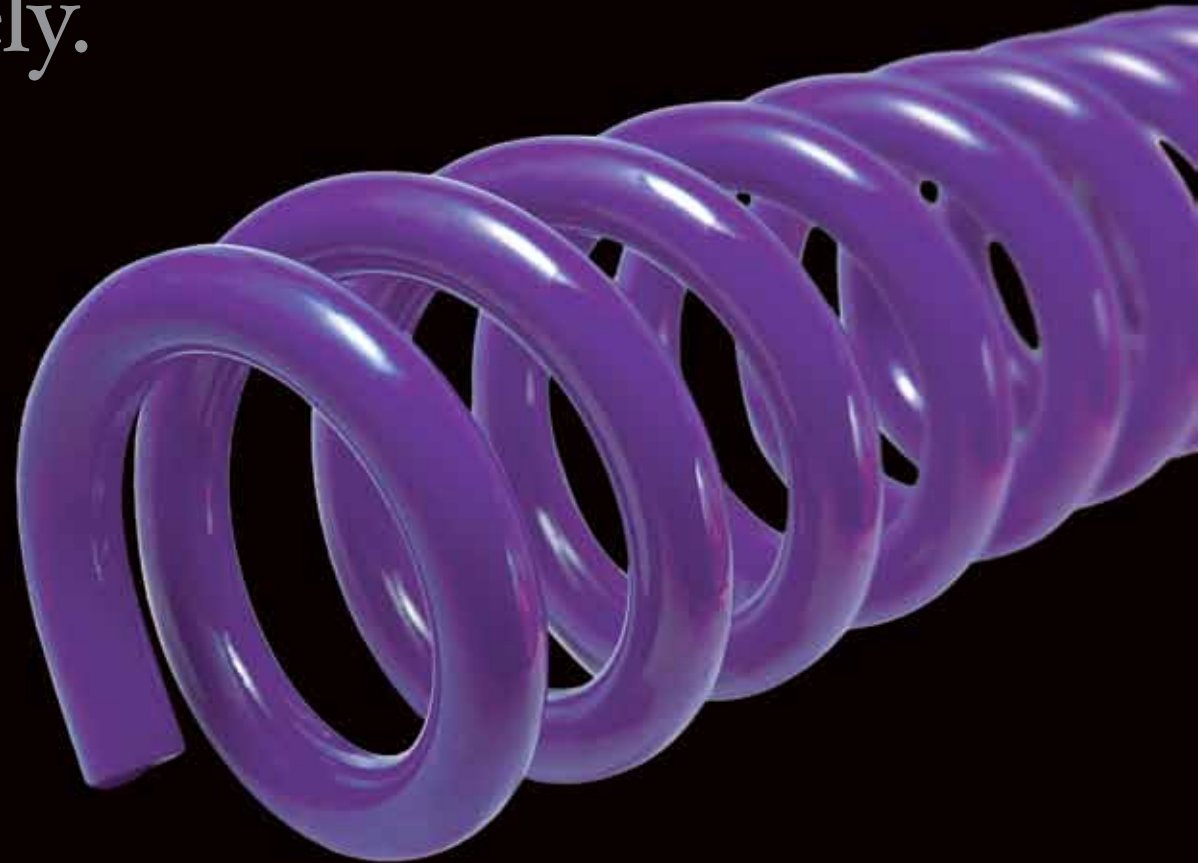


Our specialist lawyers find practical solutions to legal problems and help companies to operate and grow their businesses effectively.



Our specialist medical devices experts and experience with the industry means we are able to provide commercially-minded legal advice.

We help companies through from small start-ups with a great idea for development, to multinationals with a range of medical devices being marketed throughout Europe.

We are familiar with the regulations faced by this sector from CE marking, to clinical trials, compliance and anti-bribery, to the requirements imposed by REACH. We have represented medical device companies in dealings with a variety of regulators, from competent authorities such as the MHRA, AFSSAPS and Mdeon, to the European Commission with respect to REACH.

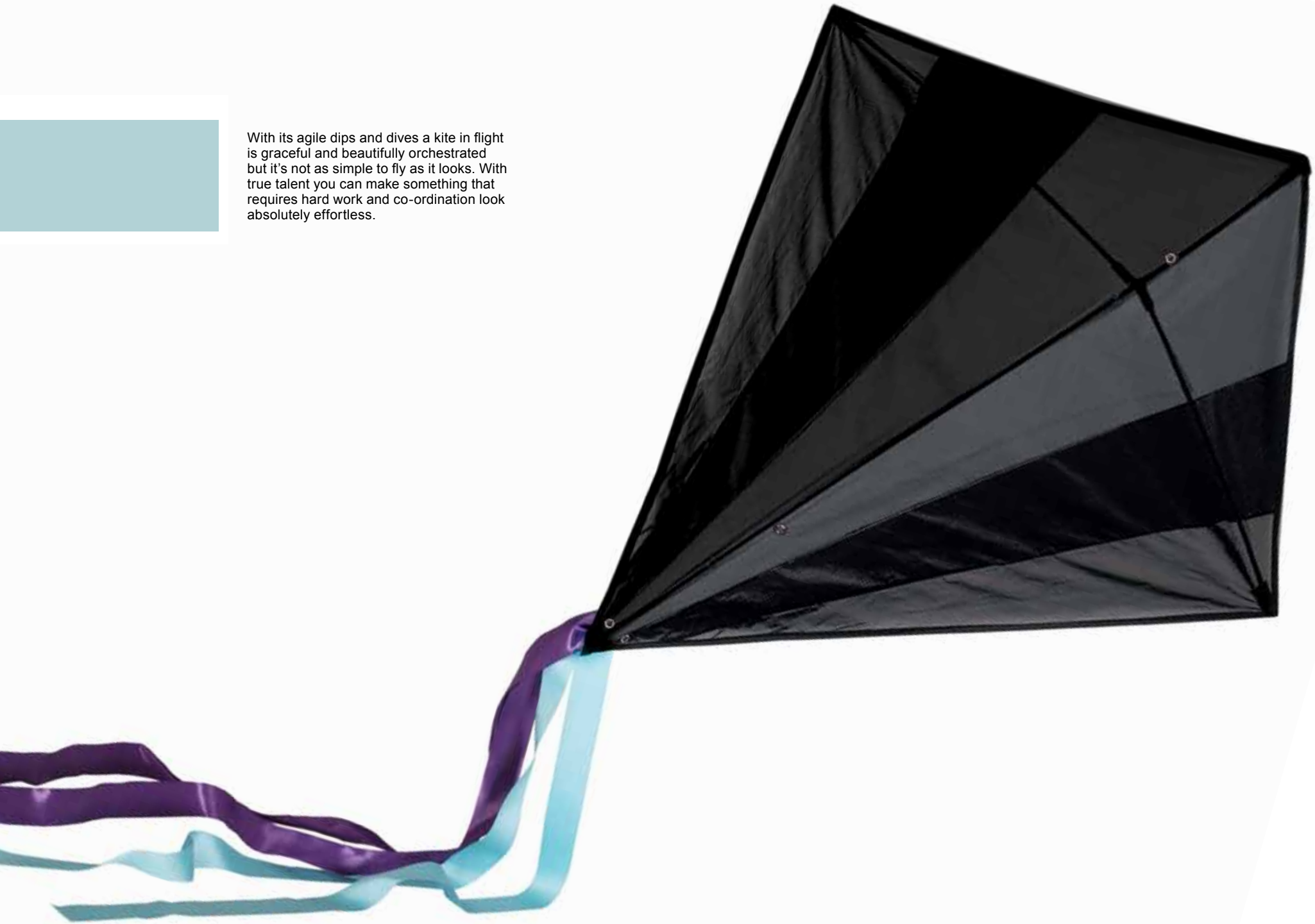
We have also been actively engaged in the drafting of codes and laws for the medical devices industry on dealings with healthcare practitioners as well as with the generally applicable anti-bribery legislation, and are experienced in negotiating with the Serious Fraud Office and the French DGCCRF when issues arise. This deep competence in the regulatory and ethical environment in which medical device companies operate forms the basis of the advice we provide to our medical devices clients.

Our medical devices industry specialism is reflected across all of the jurisdictions in which we operate through our offices in Brussels, Düsseldorf, Hamburg, London, Munich and Paris.



Field Fisher Waterhouse

With its agile dips and dives a kite in flight is graceful and beautifully orchestrated but it's not as simple to fly as it looks. With true talent you can make something that requires hard work and co-ordination look absolutely effortless.



Since the Romans' amazing discovery, magnifying glasses have been used in countless endeavours, from studying cells to gazing at stars. Sometimes, it's only by scrutinising details that you can search out the most appropriate solution.



A complex, highly regulated industry and rapidly changing market means you need lawyers who are ahead of the game.

As a medical devices company your products, manufacturing and business are subject to some substantial regulatory regimes. Gaining the necessary regulatory approvals for clinical trials and CE marking, as well as staying on good terms with local regulators can be extremely difficult. We can provide you with a clear path through these regulatory hurdles, resolve issues where you may have run into trouble and challenge the decisions of authorities or industry bodies where necessary.

There is an increasing emphasis on ethics in the conduct of companies in this sector such as the EUCOMED rules being made more stringent and several EU countries that have or are planning to institute tighter controls. This industry is also particularly affected by the EU regulation of chemicals and electrical equipment known as REACH, WEEE and RoHS.

We have the largest and most specialist REACH team in Europe, meaning we apply an expertise in this and other EU regulatory matters to help you achieve compliance.

We also have a detailed understanding of cell and tissue law, which means we can provide a comprehensive service where products include or consist of engineered cells or tissues.

Data protection and privacy is another key consideration for medical devices companies and an area of law that is changing quickly. The protection of clinical trial data is critical and our market-leading team of data protection experts, along with their 40-strong country network, will ensure that your compliance, data security and privacy policies are the best they can be.

Intellectual property (IP) management, whether this be patents, designs, trade marks or copyright is a key tool in building your business, but also a very complex one. Our leading IP team can help ensure you have the appropriate level of protection to enable you to exploit your products and have the right IP strategy in place.

How we can help you.

With our in-depth industry experience in medical devices as well as our international client base and broad range of practice areas, you can be sure we have the right knowledge, pedigree and skills to help your business. There are a wide range of areas in which we can help you including:

Regulatory and compliance

- Working with regulatory agencies on issues such as clinical trials consents, CE marking, registrations with competent authorities and pricing and reimbursement.
- Drafting compliance policies and advising on compliance and bribery issues as they arise.
- Specifically tailored training courses for your sales staff.
- Audits of your current practices to meet the stringent criteria now being imposed.
- Forming consortia for REACH registration purposes, and negotiating agreements with such consortia.
- Drafting your data security and privacy policies.

Research, clinical trials, licensing and collaboration

- Crafting agreements with third parties such as medical professionals, universities and researchers to ensure you retain your IP rights and are freely able to market your products.

- Drafting research, collaboration and licensing agreements to protect your products whilst ensuring compliance.
- Co-ordinating and drafting local and international clinical trial agreements including dealing with liability, regulations, consents and ethical issues.
- Trade mark registration, protection, defense and enforcement.
- Patent, design and copyright protection strategies.
- Management of patent infringement proceedings whether for or against you.

Supply, distribution, manufacturing and tooling

- Negotiating supply agreements for products and materials that take into account the commercial needs of your business and regulatory and compliance requirements.
- Guiding you through the contractual process involved in selling your products through sale agents, distributors or in response to government tenders, keeping within the competition law rules.
- Advice on selling through the government procurement process and acting on behavioural issues with governments.
- Advice and training to help prevent you infringing competition or antitrust laws to avoid fines and reputational damage.





Galileo and Newton are just two of the enquiring minds who have been instrumental in the development of the telescope. Being empowered by a passion to see further and know more leads to the most inspirational achievements.



From its origins on automated assembly lines, it's likely there's now a cross head screwdriver in every tool box. By being adaptable and flexible a business can move with the times and remain commercially viable.

A 'one-stop legal shop' for medical devices.

Working with us means you have the benefit of lawyers who are not only experienced in your market, but also have specialist knowledge and understanding of the industry and the issues you face. This means you can trust us to deliver workable and commercial advice that is relevant within the context of running your business.

Our lawyers really are leaders in their fields. We have experts in the regulation of the medical devices industry, procurement rules, competition law, privacy and information, technology and outsourcing, intellectual property, EU regulation and corporate finance.

Our team is based across Europe and can advise on issues across multiple-jurisdictions in Europe and the USA and across the world through our close network of specialist life sciences lawyers. This means that a single lawyer can help you manage the legal issues you face across multiple jurisdictions.

In addition to the areas already mentioned, we can also provide you with advice in other specialist areas, from managing your real estate should you be buying, selling or leasing property, to resolving disputes and employment or labour law issues and tax planning.

About us.

Field Fisher Waterhouse is a European law firm providing commercial solutions across a range of industry sectors. We have a particular focus on companies that are highly regulated and those with intellectual property and technology driven business models.

Clients choose to work with us because we can provide exceptional lawyers with industry expertise and strong commercial knowledge of their businesses.

They value our flexible approach to teamwork and that we will shape our structures and way of working to meet their specific needs.

This commercial attitude, combined with our empowering and down-to-earth style, means you can trust us to provide you with the best possible legal solutions.

Credentials aside, we believe the most important basis for a successful working partnership is a good personal relationship. The best way to find out more about us is to meet up: then you'll see that combining expertise with a straightforward and friendly approach isn't just best practice at Field Fisher Waterhouse – it's core to the way we work.



Field Fisher Waterhouse

This unsung hero has been behind some of man's greatest inventions. Sometimes, you don't know all the little jobs that are going on in the background; you just have to trust that the outcome will be outstanding.

