Luther.

Medical Technology

unyer GLOBAL ADVISORS

Our Health Care & Life Science Industry Group

Health Care & Life Science represents one of the largest and at the same time socially most important industry sectors in Germany and Europe. With currently over seven million employees and health expenditure of around EUR 380,000 million (2018) – equivalent to over 11.5% of Germany's gross domestic product – successful commercial enterprises focus on the health care industry. It is also a significant growth sector in Europe and on the world market. With its Health Care & Life Science Industry Group Luther is one of the leading advisers for your commercial success in the health care industry.

Germany's health care market comprises a large number of services and products. The focus of the health care industry is the provision of medical care to the population in addition to the pharmaceutical and medical technology industry that supports it. Furthermore, the so-called "second health care market" (home spa products, self-payer market) is making a significant and ever-increasing contribution to the health care industry.

Like no other sector of the economy, the provision of medical care to the population, the core area of the health care industry, is subject to legislative amendments nearly every year that are sometimes substantial: inpatient care (acute medicine and psychiatric hospital market) with ever new reform bills regarding hospital structure and strengthening of care and constant changes in the system of diagnosis-related groups for the remuneration of hospitals, in short DRG, and the lump-sum remuneration system in the field of psychiatry and psychosomatics, called PEPP, outpatient care and care provided by SHI-registered physicians with new structural requirements, introduced for instance by the so-called *Terminservice- und Versorgungsgesetz* (law regarding quicker appointments and better care) as well as rehabilitation medicine and provision of care for senior citizens and persons in need of care as outpatients and inpatients.

The objective is the provision of health care that is modern, patient-oriented, integrated across sectors but also very cost-efficient. At the same time, service providers and health insurance companies compete for "patients" in the face of increasing cost pressure. Providers of outpatient and inpatient services in such a heavily regulated market need an experienced and knowledgeable legal adviser who has in-depth knowledge of the market besides regulatory expertise.

We support service providers in all matters ranging from the structuring and approval of their range of medical care services offered, compliance of the service provider with the legal framework to remuneration for and billing of their services – on a comprehensive, targeted and pragmatic basis, in terms of forward-looking health care.

In combination with health care, but also operating in its own global market, the pharmaceutical and medical technology industry more than hardly any other sector is at the heart of advances in medicine and the driving force behind digitisation in health care. We advise clients on legal issues in the areas of medical technology as well as pharmaceuticals, organic products & life science, ranging from the approval, manufacture to the distribution of the products.

With regard to the new regulatory requirements of the EU Medical Device Regulation (MDR) and the German Act on Medical Devices (*Medizinproduktegesetz*, MPG) we ensure that we provide comprehensive and individual advice tailored to the clients' requirements. For example, we provide you with advice regarding the conformity assessment procedures, risk classification or CE certification process. Other examples are requirements regarding the provision of clinical data and for transition plans for old certificates.

The statutory regulations for medical devices cover any trade in such products and therefore affect both manufacturers and users of medical technology. Our expertise goes beyond regulatory issues and includes all legal aspects relating to medical technology.

In addition to their own business – promoting and maintaining human health –,"health care entrepreneurs" must today more than ever meet the challenge of keeping an eye on numerous statutory requirements, systemic regulations and guidelines for self-governing organisations, of providing statistical information and entering into cooperation agreements in order to optimise cost-effectiveness.

We also face this challenge – together with you!

Luther's Health Care & Life Science Industry Group stands for industry experience, legal expertise across sectors and sound, networked advice for the health care industry. With more than 30 specialised lawyers and tax advisers and extensive experience we assist companies in all matters relating to the health care industry. Our team is familiar with the structures in the health care market, knows the regulatory environment and understands the economic objectives of our clients. We are in constant contact on the ground with governmental decision-makers, with health insurance companies, self-governing organisations, licensing authorities and a large number of cooperation partners from the medical economy in order to develop tailor-made solutions for you.

We have the right answer for any legal question asked by our clients: our Health Care & Life Science Industry Group can call upon experts who, with their specialised expertise in the "M&A for investors/strategists", "Medical law for inpatient and outpatient service providers", "Medical technology", "Pharma, biotech and life sciences" and "Digital health" segments, ensure that a quality-based and solution-oriented advice is provided to you.

However, Luther not only provides specialised advice from the Health Care & Life Science Industry Group, but offers you comprehensive support in all other fields of law, which are important for your success and essential for complete advice.

We are looking forward to our future cooperation.

Recommended in medical law by JUVE and Legal500 Germany

JUVE 2021/2022
Health care sector: hospitals, medical care centres and pharmacies

Legal500 Germany
Industry focus health

Medical technology

Our Medical technology team advises clients on all legal matters relating to the procurement, manufacture and distribution of medical technology. Thanks to their extensive experience the team members know how to deal with the complex statutory regulations under the law relating to medical devices and are therefore able to offer the client the best possible support. Together with the other units of the Healthcare & Life Science team of experts, Luther offers a broad range of expertise and experience. Our team ensures that detailed and individual advice tailored to the respective client is provided regarding the testing and clinical assessment of medical devices. The team is familiar with the constantly changing national and international legal frameworks such as the EU Medical Device Regulation (MDR), so that we always provide our clients with competent and innovative advice despite the ever-changing legal environment.

The statutory regulations for medical devices cover any trade in such products and therefore affect both manufacturers and users of medical technology. The expertise of our team goes beyond regulatory issues and includes all legal aspects relating to medical technology. Our team is familiar with the most current topics and the clients‘ interests through the exchange of industry-specific information with leading industry associations. This ensures that optimal advice is given in every respect. In addition to providing specific advice, the team also provides comprehensive support in all other fields of law and thereby provides complete advice to our clients.

Areas of expertise in detail:

For manufacturers/importers

- Advice on all regulatory aspects of medical device law (national and international)
- Providing support when dealing with the competent authorities
- Approval of medical devices, conformity assessment,
- risk classification, clinical trials
- Advice during the placing on the market and the market introduction of new medical devices
- Advising on product recalls
- Support in dealing with Notified Bodies regarding the clinical verification of medical devices
- Legal structuring of distribution channels in Germany and abroad
- Support during contract initiation and contract negotiations, advising on concluding contracts and their implementation
- Advising on defending against claims asserted against the manufacturer under manufacturer liability in the event of problems with the manufacturer‘s medical equipment
- Law regarding remedies and aids (Firth Book of the German Code of Social Law (SGB V)
- Supplier and service contracts

For operators/users

- Advice on legal obligations regarding the use and operation of medical technology
- Advising on all contractual aspects of the procurement of medical devices
- Providing legal advice and support in the procurement process of medical devices from the competitive bidding stage, through the dialogue phase, to the drafting of the contract and the selection procedure
- Individual and innovative drafting of contracts for the procurement, management, maintenance and renewal of medical equipment
- Advice on all aspects of liability law and on the enforcement and defence of liability claims

Other areas of expertise

- Review and drafting of purchasing, delivery and service compliance advice terms and conditions (e.g. General Terms and Conditions and master agreements)
- Drafting of development, supply and quality agreements health data

- Advice on the negotiation and conclusion of distribution agreements (e.g. agency, distributor, commission or commercial broker agreements as well as franchise agreements)
- Comprehensive advice on employment law including advice on occupational safety, specific safety regulations for staff handling medical technology and provision of training courses
- Assistance with company acquisitions, mergers, joint ventures and cooperation arrangements
- Provision of support regarding patent issues, trademark law issues, know-how protection as well as all issues relating to industrial property rights
- Asserting and defending claims in arbitration and court proceedings, management of settlement negotiations taking due account of alternative possibilities for resolving the dispute
- Provision of advice regarding the competition law framework and compliance with anti-trust regulations, comprehensive compliance advice
- EU General Data Protection Regulation, German Federal Data Protection Act, sector-specific requirements for the protection of critical health data
- Preparation regarding and provision of support in the tender procedure on behalf of the company calling for tenders as well as on behalf of the bidder
- Restructuring and insolvency advice
- State aid law
- Advice in the case of insolvent contracting partners
- German and European merger control, coordination of international registrations
- Financing and advice related to restructuring
- Tax advice also on transactions and cooperation arrangements
- eHealth apps, eHealth platforms
- Funding programmes and innovation funds

Medical devices – major challenges in a dynamic market

An indication of the rapidly changing market for medical devices are not least the legislative developments in this area at the European Union level. For example, the EU Medical Device Regulation and the Regulation (EU) on vitro diagnostic medical devices were adopted in 2017. In addition, there are numerous national and international laws, regulations and recommendations, which currently must also be observed by market participants. The definition of medical devices also shows the variety existing in the industry sector. Under the Medical Device Regulation of the European Union (Regulation (EU) 2017/745 of 5 April 2017) the term 'medical device' stands for different product types intended to be used for specific medical purposes. These include the diagnosis and treatment of disease, injury or the replacement or modification of the anatomy. However, a product is only deemed to be a medical device if its principal intended action is not achieved by pharmacological, immunological nor metabolic means, in or on the human body. This repeatedly gives rise to definition issues, for example, with regard to "pharmaceutical law" and the legal issues arising from this. Irrespective of the foregoing, products used to control and support conception as well as such products needed for the cleaning, disinfection or sterilisation of the medical devices as defined shall also be deemed to be medical devices.

Against this background legal issues arise for the practice in the regulatory, applications and services, production, research/future areas as well as with regard to compliance and the internal organisation that require legal solutions.

Regulatory

The regulatory framework prescribed by the legislator will be redefined in future by the EU Medical Devices Regulation and the Regulation (EU) on vitro diagnostic medical devices that will become binding from 26 May 2022 (Regulation (EU) 2017/746 of 5 April 2017). Furthermore, the EU General Data Protection Regulation (GDPR) remains crucial, particularly with respect to critical patient data.

In this context, it is important that the market participants determine whether their products qualify as medical devices within the meaning of the Regulation and to what extent a classification and conformity assessment are required in order to bring a product to market. Due to changes in the Annex to the Medical Device Regulation cases may also arise where reclassification is required resulting in stricter requirements having to be met in future.

New challenges will arise for manufacturers on dealing with the newly introduced Notified Bodies or the appointment of persons responsible for regulatory compliance within the meaning of Article 15 of the EU Medical Device Regulation.

Applications and Services

Established as well as newly developed devices fall under the “Applications“ and “Services“ headings. Examples of these include robot technology (surgery robots), augmented reality, interventional medical technologies, home care, telemedicine, medical apps and neural engineering. All these topics give rise to issues regarding market access requirements and liability.

Production

The production of medical devices and use of 3D printing technology is set to increase in importance in the future. At the same time, it should be noted that the requirements to be complied with will become stricter under the EU Medical Device Regulation. Up until now it was mostly the case that implantable devices produced with a 3D printer did not generally need to be certified by a Notified Body. With the applicability of the EU Medical Device Regulation this will change such that 3D printed implantable devices will be equivalent to other medical devices. The resulting required classification should give rise to significant additional expense for manufacturers. We support you with our legal expertise in meeting these challenges.

Research/Future

The medical devices sector is also subject to constant development and the invention of new technologies and discovery of new possibilities for diagnosis, treatment and curing. “Living“ implantable devices that grow with and adjust to the body such as heart valves, skin, cartilage or also bones should already be mentioned in this context today. It is especially important that manufacturers also bear in mind patent and copyright law issues in this area. There are also significant opportunities to obtain funding in this field. Tender procedures and their course in particular must be taken into account by manufacturers in this regard.

Compliance and Internal Organisation

The issue of compliance must not be ignored where medical devices are manufactured and traded. Compliance generally means observance of laws and regulations. Within a company these are rules and guidelines that need to be drafted and which shall be binding on all employees. This leads onto the need for an internal organisation and, for example in this case, compliance with adequate hygiene standards.

Conclusion

This overview shows that the medical devices market is developing rapidly at many levels. This is combined with an increasingly complex legal environment. Our advisory practice shows that the objectives of our clients can be effectively achieved by a comprehensive range of advisory services offered by a highly specialised full-service law firm. Take advantage of our many years of experience and industry expertise.

We are also close to you

Selected references

Your Contacts

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Dr Kuuya Josef Chibanguza is a certified specialist in international business law. He studied law at the University of Osnabrück (Germany), completing at the same time a Bachelor of Laws (LL.B.) programme in business law. He was awarded his doctorate for a thesis on a European law topic. Kuuya Josef Chibanguza joined Luther as a lawyer in 2013.

In addition to working as a lawyer at Luther, Kuuya Josef Chibanguza also works as a visiting lecturer and is the author of various legal papers.

Areas of Practice

Dr Kuuya Josef Chibanguza is frequently recommended as an advisor to national and international clients when it comes to minimising (product) liability risks in the context of digitalisation (Industry 4.0). In a series of events developed by him regarding “Legally sound project management”, he regularly holds workshops, in particular on the question of how to minimise risks in purchasing and distribution. Kuuya Josef Chibanguza additionally advises national and international clients on contract, commercial and distribution law. He has special expertise in dispute resolution, in and out of court, including as an advisor in arbitration proceedings.

Kuuya Josef Chibanguza is a member of Luther’s South Africa / Africa Desk. He is also Director of the Interdisciplinary Institute for Automated Systems (RifaS) in Hanover. In addition, Dr. Chibanguza is co-editor of the handbook “Künstliche Intelligenz” (Artificial Intelligence), published by Nomos-Verlag, as well as the “Zeitschrift für das Recht der digitalen Wirtschaft” (ZdiW).

Your Contacts

Dr Hendrik Bernd Sehy

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Dr Hendrik Bernd Sehy studied law from 1998 to 2003 at the Ruprecht Karl University in Heidelberg, Germany. He spent part of his traineeship at an international American economic law firm in Frankfurt and worked in the Corporate/M&A Department. He was admitted to the bar and joined the Luther team in 2006. In 2014/2015, Hendrik Sehy completed the training course to become a certified specialist in medical law and is a certified specialist in medical law since 2018. He is a member of the German association dealing with the laws governing registered physicians who treat persons insured under the statutory health insurance system (Deutsche Gesellschaft für Kassenarztrecht e.V.), and he is also a member of the medical law working group of the association of Hanover-based lawyers and civil-law notaries (Rechtsanwalts- und Notarverein Hannover e.V.).

Areas of Practice

Dr Hendrik Bernd Sehy advises mostly companies that operate in the health care market on all issues pertaining to corporate and medical law, as well as during transaction processes and restructurings. He primarily advises service providers, such as hospitals, medical care centres, large medical practices, and rehab and nursing care providers, inter alia on regulatory and financing issues, and he further advises the public sector on structural measures in the health care industry. Hendrik Sehy also provides advice to start-ups and well-established manufacturers of medical products, for example, when they launch new products or with regard to reimbursement issues.

Hendrik Sehy additionally focuses on advising the public sector (inter alia, German states, municipalities and medical associations) on structural measures (in particular in the hospital market) or other regulatory issues relating to the health care industry and on providing support during arbitration proceedings pertaining to social law.

Together with Dr Eva Rütz, Dr Hendrik Sehy heads the working group “In-patient and out-patient service providers”, which is part of Luther’s Health Care & Life Science industry group.

Your Contacts

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Martina Steude studied law at the University of Kiel (Germany) with an emphasis on health law and, in addition, obtained a Master of Law degree in Cape Town (South Africa). She worked for the Hamburg Medical Association as part of her legal training and later worked as an inhouse lawyer for a private hospital group.

Areas of practice

Martina Steude mainly advises companies in the health care market on corporate and medical law issues. In addition to acting as an advisor in transaction and restructuring processes, she also advises providers of inpatient and outpatient services on cooperation structures and on licensing and remuneration issues.

Hits the mark. Luther.

Luther Rechtsanwaltsgesellschaft mbH is one of the leading corporate law firms in Germany. With some 420 lawyers and tax advisors, we can advise you in all fields of German and international corporate law. In addition to having offices in every economic centre throughout Germany, we are also present in 11 locations abroad: in Brussels, London and Luxembourg in Europe, and in Bangkok, Delhi-Gurugram, Ho Chi Minh City, Jakarta, Kuala Lumpur, Shanghai, Singapore and Yangon in Asia.

Our advisory services are tailored to our clients' corporate goals. We take a creative, dedicated approach to achieving the best possible economic outcome for each of our clients. The name "Luther" stands for expertise and commitment. With a passion for our profession, we dedicate all our efforts to solving your issues, always providing the best possible solution for our clients. Not too much and not too little – we always hit the mark.

We know how crucial it is to use resources efficiently and to plan ahead. We always have an eye on the economic impact of our advice. This is true in the case of strategic consulting as well as in legal disputes. We have complex projects on our agenda every day. At Luther, experienced and highly specialised advisors cooperate closely in order to offer our clients the best possible service. Thanks to our fast and efficient communication, permanent availability and flexibility, we are there for you whenever you need us.

Luther has been named "Law Firm of the Year: Germany 2021" and also "European Law Firm of the Year 2021" by The Lawyer, one of the most well-known legal magazines worldwide.

Lawyers and tax advisors

420

Locations

21

Long-standing connections to commercial law firms worldwide

Offices in international financial centres and investment locations

About unyer

unyer, founded by Luther and Fidal in 2021, is a global organisation of leading international professional services firms. Besides law firms, unyer is also open to other related professional services, especially from the legal tech sector. unyer is based in Zurich as a Swiss Verein. unyer is globally connected but has strong local roots in their respective markets.

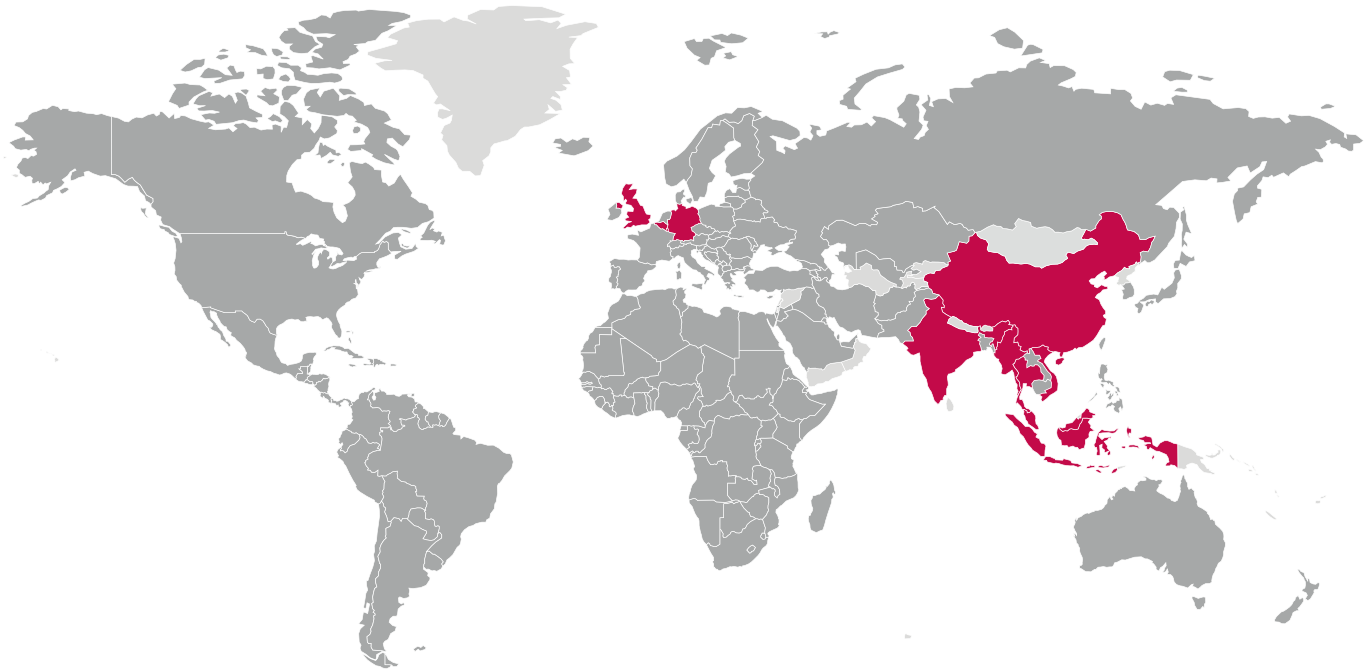
unyer has an exclusive approach and only accepts one member firm from each market. unyer members offer its clients full services across all jurisdictions with a compelling industry focus. The organisation has an annual turnover of more than EUR 650 million and includes over 2,550 lawyers and advisors in more than 10 countries in Europe and Asia. In September 2021, Pirola Pennuto Zei & Associati joined the international organisation. In the spring of 2023, the Austrian law firm KWR joined the group.
www.unyer.com

MEMBER OF unyer

Our locations

We have a global outlook, with international offices in 11 key economic and financial centres in Europe and Asia. We also maintain close relationships with other commercial law firms in all relevant jurisdictions. Luther is a founding member of unyer (www.unyer.com), a global organisation of leading professional services firms that cooperate exclusively with each other. This way, we ensure a seamless service for our clients throughout their demanding international projects.

Our partner firms are based in Africa, Australia and New Zealand, Europe, Israel, Japan and Korea, the Middle East, Russia and the CIS, South and Central America, the US and Canada.



- Luther locations
- Best friends

Our locations

Bangkok
Berlin
Brussels
Cologne
Delhi-Gurugram
Dusseldorf
Essen
Frankfurt a.M.
Hamburg
Hanover
Ho Chi Minh City
Jakarta
Kuala Lumpur
Leipzig
London
Luxembourg
Munich
Shanghai
Singapore
Stuttgart
Yangon

Our industries

We focus on advising transactions with respect to targets in five industries.

Conventional or renewable energies: We work efficiently and sustainably.

With our expertise, we have our finger on the pulse of time.

We connect today with tomorrow.

We understand what gets you moving and can set you on the right course.

We lay the foundation for you to build on.

Our practice areas

- Antitrust Law
- Capital Markets & Banking
- Commercial & Distribution Law, Product Liability/ Product Compliance
- Complex Disputes
- Compliance & Internal Investigations
- Corporate/M&A
- Data Protection Law
- Employment Law
- Energy Law
- Environment & Planning Law Regulatory
- Financial Services Investment Funds & Alternative Investments
- Insurance Law
- International Trade Law
- IP & Copyright Law
- IT Law
- Media & Entertainment
- Notarial Services
- Public Procurement Law
- Public Subsidies/ State Aid Law
- Real Estate
- Restructuring & Insolvency
- Start-ups & Venture Capital
- State, Administration, Public Undertakings
- Tax Law
- Telecommunications Law
- White-Collar Crime & Tax Offences

Our awards

JUVE

In the 2022/2023 JUVE Guide to Commercial Law Firms, 52 lawyers from Luther were recommended, and 10 of these were also listed as “leading advisors”. The legal publisher JUVE ranked Luther in 31 areas of law. In 2022, Luther was nominated for the JUVE award “Employment Law” as well as “Real Estate” and was named “Law Firm of the Year” by JUVE in 2019. In the past, Luther already won the JUVE award “Law Firm of the Year 2017 for Environmental and Regulatory Law”.

The Legal 500

The Legal 500 Germany 2023 recommends Luther in 30 areas of law, with “Top Tier” rankings in two of these areas. 72 lawyers are being recommended, 12 of whom have been specially recognised as “Leading Individual” or “Next Generation Partner”. Luther has also been included for Germany in the first edition of **The Legal 500 Green Guide EMEA 2022**. This guide provides an overview of law firms’ engagement with sustainability, including both work for clients as well as firms’ own best practices and initiatives.

Chambers

In 2023, Luther was recognised by Chambers Europe for 13 practice areas in Germany as well as in two practice areas in Luxembourg. Moreover, 15 partners were included in the Individual Ranking. Additionally, in 2023, Luther was recognised by Chambers Global in three advisory areas in Germany and Myanmar, while five partners were also included in the Individual Ranking.

The Lawyer European Awards

Luther has been named “Law Firm of the Year: Germany 2021” and also “European Law Firm of the Year 2021” by The Lawyer, one of the most well-known legal magazines worldwide.

Kanzleimonitor

Kanzleimonitor 2022/2023 recommends Luther in 25 areas of law and has also included 16 Luther lawyers among the recommended lawyers mentioned by name.

„Best Lawyers in Germany 2024“

For the year 2024, 99 lawyers have been recommended by Luther as “Best Lawyers in Germany 2024”, an award presented by the US publisher “Best Lawyers” in cooperation with the German Handelsblatt, including one partner as “Lawyer of the Year” for his area of law, and 19 colleagues who have received the recommendation “Best Lawyers - Ones to Watch”.

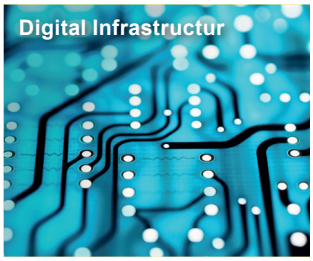
WHO’S WHO LEGAL

WHO’S WHO LEGAL listed 21 lawyers in December 2022, four of whom were recognised as Thought Leaders, which is the highest award, and three of whom were named Future Leaders.

Digitalisation

The digital revolution is well under way. In a highly competitive market new business models are always being developed and existing processes are continually being challenged. Groups, medium-sized businesses and start-ups are all looking for the best possible ways to position themselves in this environment. In this way, new, innovative forms of cooperation are constantly being created. This revolution is being driven by numerous recent technological developments: cloud computing, digital platforms, Big Data and artificial intelligence, the Internet of Things and blockchain technology.

Luther advises on all legal topics relating to digital business models, agile architectures and technical levers. Our team provides support in all phases of the necessary transformation processes within the company, the law firm or the group, from strategic dialogue to conceptual work and the realignment of value chains, also including the subsequent change process. When providing advice, the Luther team also considers relevant topics and changes in commercial and distribution, employment, IT and data protection law.



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For reasons of better legibility, the simultaneous use of gender-specific language forms is dispensed with. Corresponding terms apply in principle to all genders in the sense of equal treatment. The abbreviated form of language has editorial reasons and does not imply any valuation.

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Luther.

Bangkok, Berlin, Brussels, Cologne, Delhi-Gurugram, Dusseldorf, Essen, Frankfurt a.M., Hamburg, Hanover, Ho Chi Minh City, Jakarta, Kuala Lumpur, Leipzig, London, Luxembourg, Munich, Shanghai, Singapore, Stuttgart, Yangon

You can find further information at:
www.luther-lawfirm.com
www.luther-services.com

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