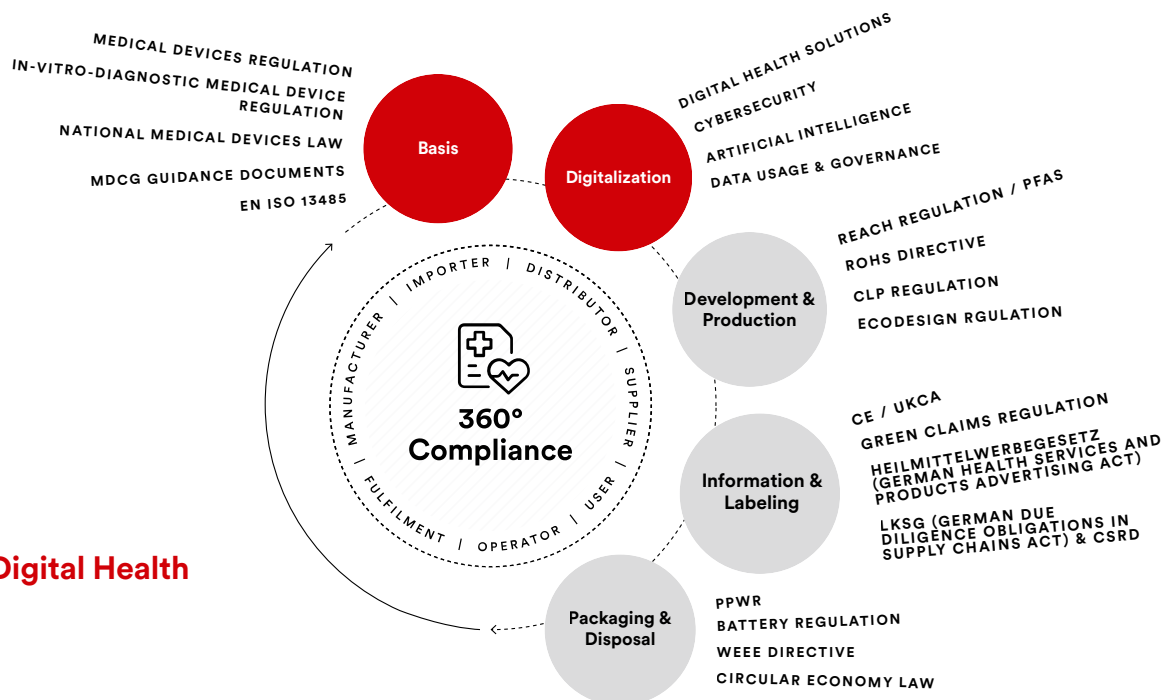


Medical Devices - 360° Compliance

The healthcare sector faces new challenges due to the increasing connectivity of products and growing regulatory complexity. Our 360° compliance approach integrates digital aspects from the very beginning and addresses regulatory requirements throughout the entire product lifecycle.

Challenge

The European Economic Area is distribution and target market for medical devices, IVDs, and digital health solutions. The MDR and IVDR constitute the regulatory framework for the distribution of these products. However, in addition to these requirements, further product-specific and company-specific obligations must be observed throughout the entire product life cycle, ranging from development and manufacturing to product information and labeling, as well as packaging and disposal of products and services. As digitalization increases, so does regulatory complexity. New tools such as health apps, smart gadgets, and AI support and accompany diagnosis and therapy. Data-driven systems are also shaping new business models. In this context the requirements under medical device law and digital law are intertwined. The European Green Deal has introduced additional requirements that are relevant to medical devices, such as the Ecodesign and Packaging Regulations, the REACH Regulation, and the RoHS Directive. Through the CE marking, manufacturers also confirm that their products comply with these regulations.



**Product Liability,
Product Safety & Digital Health**

Solution: 360° Compliance

reuschlaw advises stakeholders in the healthcare ecosystem on the applicability of relevant European and national regulations governing development and production, as well as placing on the market, distribution, post-market surveillance, and disposal of medical devices and services. Our 360° compliance service provides you with an overview of the applicable obligations in each specific case. We also provide support with audit-compliant contract drafting, communication with Notified Bodies and regulatory authorities, as well as FSMA and recall management.

Get in touch with us!

Please feel free to contact us at any time if you need our assistance or have any questions. We are happy to explain our approach to you in a one-on-one conversation.