Extract

While healthcare digitalisation brings enormous upsides to patients by delivering faster, more efficient and more comfortable solutions to their health problems than analogue or human-driven healthcare, it also results in new and unforeseen types of incidents. As in other technology-driven industries, product malfunctions may occur in HealthTech and put patients' health and safety at risk despite all due care. This chapter examines key challenges posed by the EU product liability legislation for HealthTech products and businesses. It covers recent EU initiatives in this area and describes the remaining grey zones. The chapter further considers the interplay between the product safety and regulatory compliance required under the Medical Devices Regulation and product liability standards. It highlights the challenges that manufacturers must face, but also the opportunities that the Regulation offers for HealthTech companies seeking to protect their businesses against product liability risks.
Product liability is the area of law in which manufacturers, distributors, suppliers, retailers, and others who make products available to the public are held responsible for the injuries those products cause. Although the word “product” has broad connotations, product liability as an area of law is traditionally limited to products in the form of tangible personal property. Products liability can also be a life-or-death matter from the manufacturer’s perspective. In 2009, Bloomberg BusinessWeek reported that the costs of product safety for manufacturing firms can be enormous: “Peanut Corp., based in Lynchberg, Va., has been driven into bankruptcy since health officials linked tainted peanuts to more than 600 illnesses and nine deaths. Mattel said the first of several toy recalls it announced in 2007 cut its quarterly operating income by $30 million. How does the separation of production from consumption affect products-liability issues? What other changes in production and consumption have caused the need for the development of products-liability law? Product compliance and reliability is key to sustainable trading performance and reputation. There are few more delicate situations to handle when things go seriously wrong with a product on the market. Follow Product Liability. Our product liability team, led by Andrew Masterson and Jacqueline Harris, covers the full range of product related challenges including: Civil claims and defence – bringing and defending financial claims for losses due to product defects (both widespread, and isolated but serious) including handling quantum via our forensic accounting team. Product regulatory compl...