Summary:

The subject of the doctoral dissertation is to discuss the legal grounds for liability for damage caused by a dangerous medical product. In the Polish legal system, liability for a dangerous product is regulated in art. 449^1-449^{10} of the Civil Code, which implement the Council Directive of 25 July 1985 on the approximation of laws, regulations and administrative provisions of the Member States relating to liability for defective products (85/374/EEC). Striving to harmonize the private law of the European Union, we often encounter problems related to the adaptation of national laws to those of the European Union. They were analyzed in chapter 1 of the dissertation.

After discussing the preliminary issues, the legal grounds for liability for damage caused by a dangerous medical product were thoroughly analyzed. Chapter 2 of the dissertation discusses the definition of a producer, which cannot be analyzed without first discussing the notions of an entrepreneur and economic activity. It was not less important to indicate the obligations of producers other than information obligations. Chapter 3 of the dissertation was devoted to information obligations. This chapter focuses mainly on the principles of labeling medical devices and the consequences of acting against the manufacturer's recommendations. One of the key chapters of the dissertation is chapter 4, in which an attempt was made to define the product. Not only the product definition in general was analyzed, but also the definition of a dangerous product. Other important issues that were discussed in chapter 4 of the dissertation are those concerning the placing of a product on the market, the concept of the so-called "risk of progress" and an indication of the types of medical products. Chapter 5 describes the entity to which the damage may be caused, i.e. the aggrieved party. Due to the fact that the aggrieved party is often not related to the producer by any contractual relationship, it was necessary to carefully describe the situation of the so-called *bystanders* and indirectly injured persons. Chapter 6 was devoted to the prerequisites of liability, which include the defectiveness of a dangerous product placed on the market (in other words, a causative event), damage and a causal link between them. While discussing the issues of fundamental importance for civil law, attention has been focused primarily on a thorough analysis of the concept of damage, which, within the meaning of the provisions on product liability, is both damage to property and personal injury. A significant part of chapter 7 was devoted to the characterization of entities considered as a producer (in other words, responsible entities, such as a producer), which include the manufacturer of the material, raw material or component of the product, alleged manufacturer, importer and authorized representative, vendor, supplier, distributor, storehouse,

and even in some cases a third party. Next, the issue of the presumption of producer responsibility and the cases of limitation and exclusion of producer responsibility, which constitute exceptions to the general prohibition of limiting or excluding this liability, were considered. The subject of chapter 8 is the limitation of claims due to the aggrieved party against the producer. In addition to the general characteristics of the statute of limitations, attention was drawn to the latest English and French jurisprudence on this issue. Chapter 9 is devoted to other forms of liability for damages. It was necessary to resolve the conflicting grounds of liability of many different entities – the hospital, the doctor and, of course, the producer. In the last chapter of the dissertation, which is a summary of previous arguments, numerous *de lege ferenda* remarks were made both with regard to the provisions of the Civil Code and with regard to the provisions of Directive 85/374/EEC.