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Producer’s Liability for Defective Medical Devices in Light of Council Directive 85/374/EEC

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Abstract : Medical devices are products used for medical purposes and aimed to operate in the human body, sometimes even inside the human body. Therefore, they can become particularly risky products, and some of the injuries caused by medical devices can have serious effects on the person’s health or body, even leading to death. Because they fit in the category of 'products' as described in Article 2 of Council Directive 85/374/EEC of 25 July 1985, concerning liability for defective products, the liability of the manufacturer of medical devices follows the rules of strict liability as long as one of the defects covered by the directive is at stake. The directive is not concerned with the product’s efficiency, but instead with the product’s safety, although in what regards medical devices (the same being valid for drugs) the two concepts frequently go together, and a lack of efficiency can result in a lack of safety. In the particular case of medical devices, the most debatable defects are the ones related with erroneous or non-existing information and the so-called development defects. This paper analyses how directive 85/374/EEC applies to medical devices, which defects are covered by its regulation, and which criteria can be used to evaluate the product’s safety. Some issues are still to be clarified, even though the decisions from the European Court of Justice and from national courts are valuable tools to understand the scope of directive 85/374/EEC in what regards medical devices.

Keywords : medical devices, producer’s liability, product safety, strict liability
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