

France – Conseil d'État (Council of State) – Decision No 327449 – 12/03/2012

Public health – Scope of Council Directive 85/374/EEC – Liability without negligence on the part of public health establishments on account of the failure of a device or product used in providing care to patients

In a ruling handed down on 4 October 2010 in the context of a dispute between a hospital and one of its patients surrounding the use during a surgical procedure of a defective heatpad, the Conseil d'État had submitted a reference to the ECJ for a preliminary ruling as to whether Council Directive 85/374/EEC of 25 July 1985 permitted the application of a system of liability based on the specific situation of patients in public health establishments insofar as it recognised their right to claim compensation for damage caused by defective products or devices used, even in cases in which the establishments themselves were not at fault.

The ECJ held that liability on the part of a service provider using, in the context of provision of services such as care provided in a hospital, defective devices or products of which it was not the producer within the meaning of the provisions of Article 3 of the directive, and causing damage to the recipient of the service as a result, did not fall within the scope of the stated directive. However, the ECJ nevertheless found that said directive did not preclude a Member State from introducing a system whereby the service-provider could be held liable.

Applying the principle whereby the hospital was to be held liable, despite the absence of any negligence on its part, for damage caused to patients by defective healthcare products and devices used by it, without prejudice to any action which may be taken against the producer of the products/devices, the Conseil d'État found the hospital guilty.