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Liability of the notified body towards end users as a consequence of the conformity assessment procedure of medical devices

Judgement of the Court of Justice, of 16 February 2017, C-219/15

Background

The judgement in question concerns a claim brought by Mrs. Schmitt against TÜV Rheinland, a notified private body which is qualified in Germany for the conformity assessment of medical devices.

Mrs Schmitt had to remove the breast implants that had been subject to a conformity assessment by the notified body, after the competent French authority established that the breast implants did not comply with the quality standards. Given the fact that the manufacturer was insolvent, Mrs. Schmitt claimed compensation for non-material damages from that notified body, arguing that it did not carry out unannounced visits, final inspections of the products and that it did not check the delivery notes and invoices which evidenced that the manufacturer did not use an approved form of silicone.

The Court of first instance rejected the contractual and non-contractual liability of the notified body since Mrs. Schmitt was not part of the contract concluded between such body and the manufacturer and since the notified body did not act negligently in carrying out visits announced in advance to the manufacturers. This decision was appealed and the appeal court referred the question to the Court of Justice for a preliminary ruling asking whether such notified bodies are obliged, under European law, to undertake unannounced inspections, to examine the design of the products and/or to examine the manufacturer's business records.

Court of Justice conclusions

The Court of Justice starts by reminding that European law confers wide inspection and control powers to these notified bodies, but it does not impose a general obligation to carry out unannounced inspections, to examine devices nor to examine the manufacturer's business records.

However, the Court also reminds that the purpose of the Directive 93/42 is to protect the safety of persons and that although these notified bodies are provided with an adequate degree of discretion, they are subject to a general surveillance obligation. Such obligation implies that the body must take appropriate measures if it gets evidence indicating that a medical device may not comply with the requirements laid down in the European law. For that reason, the eventual liability of such bodies cannot be excluded.

Considering that the purpose of the Directive is not to govern the conditions under which the end users of medical devices may be able to obtain compensation for culpable failure by those bodies, the Court concludes that the conditions under which culpable failure by that body to fulfil its obligations under the directive may give rise to liability on its part are governed by the national law of each member state.