Court of Justice of the European Union
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Press and Information

Judgment in Case C-219/15
Elisabeth Schmitt v TÜV Rheinland LGA Products GmbH

The Court of Justice delivers its judgment in the case involving breast implants made of inferior quality industrial silicone

In 2008, Mrs Elisabeth Schmitt had breast implants manufactured in France fitted in Germany. After the French authorities established in 2010 that the French manufacturer had produced breast implants using industrial silicone which did not comply with quality standards, Mrs Schmitt had the implants removed. In the meantime, the manufacturer became insolvent.

Before the German courts, Mrs Schmitt has claimed from TÜV Rheinland, the body appointed by the manufacturer to audit its quality system for the purposes of EC certification, €40 000 by way of compensation for non-material damage. She has also sought a declaration that TÜV is liable for any future material damage. In her view, an inspection of the delivery notes and invoices would have enabled TÜV to ascertain that the manufacturer had not used an approved form of silicone.

According to the Bundesgerichtshof (Federal Court of Justice, Germany), in order for TÜV to incur liability, it must have infringed a rule conferring legal protection or a contractual obligation. In order to establish whether there was such an infringement, the Bundesgerichtsthof has asked the Court of Justice to interpret, as a preliminary issue, the relevant EU legislation, namely Directive 93/42 concerning medical devices.[1] That directive harmonises the requirements to be met by medical devices, such as breast implants, in order for them to be placed on the market. It governs, inter alia, the procedure relating to the EC declaration of conformity and the tasks and obligations of notified bodies involved in the quality assurance system.

By today's judgment, the Court finds that, under that directive, **a notified body, such as TÜV**, which is involved in the procedure relating to the EC declaration of conformity, **is not under a general obligation to carry out unannounced inspections, to examine devices and/or to examine the manufacturer's business records. However, in the face of evidence indicating that a medical device may not comply with the requirements laid down in the directive, the notified body must take all the steps necessary** to ensure that it fulfills its obligations under the directive.[2]

The Court also finds that the **purpose of the notified body's involvement** in the procedure relating to the EC declaration of conformity **is to protect the end users of medical devices**. However, **the conditions under which culpable failure by that body** to fulfill its obligations under the directive in connection with that procedure **may give rise to liability on its part vis-à-vis end users are governed by national law**, subject to the principles of equivalence and effectiveness.

[1] Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ 1993 L 169, p. 1), as amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council of 29 September 2003 (OJ 2003 L 284, p. 1). That directive was amended by Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 (OJ 2007 L 247, p.21). However, all those **amendments** concern provisions which were to be applied **from 21 March 2010** and are therefore **irrelevant for the purposes of the present proceedings**.

[2] Those obligations include that of ensuring that the manufacturer duly fulfils the obligations imposed by the approved quality system and establishing, where appropriate, whether EC certification may be maintained.

NOTE: A reference for a preliminary ruling allows the courts and tribunals of the Member States, in disputes which have been brought before them, to refer questions to the Court of Justice about the interpretation of European Union law or the validity of a European Union act. The Court of Justice does not decide the dispute itself. It is for the national court or tribunal to dispose of the case in accordance with the Court's decision, which is similarly binding on other national courts or tribunals before which a similar issue is raised.

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