Reports of Cases

OPINION OF ADVOCATE GENERAL
SHARPSTON
delivered on 15 September 2016[1]

Case C-219/15

Elisabeth Schmitt
v
TÜV Rheinland LGA Products GmbH

(Request for a preliminary ruling from the Bundesgerichtshof (Federal Court of Justice, Germany))

(Industrial policy — Checks on the conformity of medical devices by a notified body appointed by the manufacturer — Obligations of that body — Breast implants manufactured using defective silicone — Responsibility of the notified body)

Introduction

1. By this request for a preliminary ruling, the Court is asked for guidance on the extent to which a notified body under Directive 93/42 concerning medical devices[2] may be liable to third parties who have been injured or suffered loss as a result of a failure on that body's part to perform its duties under that directive. If and to the extent that such liability may arise, the Court is also asked to clarify the nature of the duties incumbent on such a body when performing its functions under the directive.

1 — Original language: English.

2 — Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ 1993 L 169, p. 1). The directive has been amended several times since its adoption. The version relevant to the events in the main proceedings is the version as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council of 29 September 2003 adapting to Council Decision 1999/468/EC the provisions relating to committees which assist the Commission in the exercise of its implementing powers laid down in instruments subject to the procedure referred to in Article 251 of the EC Treaty (OJ 2003 L 284, p. 1). While Directive 93/42 has since been amended by Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 (OJ 2007 L 247, p. 21), which came into force on 11 October 2007, the measures to be applied under that directive were, by virtue of Article 4, to be applied only with effect from 21 March 2010. Directive 93/42 is itself proposed to be replaced by a new regulation of the European Parliament and of the Council on medical devices. See, most recently, Council Press Release 283/16 of 25 May 2016.

Legal framework

EU law

Directive 93/42

2. The recitals of Directive 93/42 state, in particular:

— that measures should be adopted in the context of the internal market; and that the internal market is an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured (recital 1);

— that national provisions for the safety and health protection of users with regard to the use of medical devices should be harmonised in order to guarantee the free movement of such devices within the internal market (recital 3);

— that medical devices should provide users with a high level of protection and that the maintenance or improvement of the level of protection attained in the Member States is one of the essential objectives of the directive (recital 5);

— that the application of the modules for the various phases of the conformity assessment procedures established as part of the New Approach [3] to medical devices enables the responsibility of manufacturers and notified bodies to be determined during those procedures (recital 14);

— that medical devices should be grouped into four product classes, with Class III being reserved for the most critical devices for which explicit prior authorisation with regard to conformity is required for them to be placed on the market (recital 15); and

— that medical devices should, as a general rule, bear the CE mark to indicate their conformity with the provisions of the directive to enable them to move freely within the Community and to be put into service in accordance with their intended purpose (recital 17).

3. Article 1 of Directive 93/42 provides in particular:

‘1. This Directive shall apply to medical devices and their accessories. …

2. For the purposes of this Directive, the following definitions shall apply:

(a) “medical device” means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, … intended by the manufacturer to be used for human beings for the purpose of:

…

— investigation, replacement or modification of the anatomy or of a physiological process,

…

3 — See further point 24 et seq. below.

(f) "manufacturer" means the natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party.

…

(h) "placing on the market" means the first making available in return for payment or free of charge of a device other than a device intended for clinical investigation, with a view to distribution and/or use on the Community market, regardless of whether it is new or fully refurbished;

…'

4. Article 2 of Directive 93/42 provides that Member States are to take all necessary steps to ensure that devices may be placed on the market and/or put into service only if they comply with the requirements laid down in the directive when duly supplied and properly installed, maintained and used in accordance with their intended purpose.

5. Article 3 of Directive 93/42 states that medical devices must meet the essential requirements set out in Annex I which apply to them, taking account of the intended purpose of the devices concerned.

6. Article 8(1) of Directive 93/42 imposes obligations on Member States in relation to medical devices bearing the CE marking which have been correctly installed, maintained and used for their intended purpose but may nonetheless compromise the health and/or safety of users. They are to take all appropriate interim measures to withdraw such devices from the market or prohibit or restrict their being placed on the market or put into service and immediately to inform the European Commission of any such measures, indicating the reasons for their decision.

7. Article 9 of Directive 93/42 provides for medical devices to be divided into Classes I, IIa, IIb and III.

8. Article 10 of Directive 93/42 requires Member States to take the necessary steps to ensure that any information brought to their knowledge regarding, inter alia, any malfunction or deterioration in the characteristics and/or performance of a Class I, IIa, IIb or III medical device is recorded and evaluated centrally and immediately to inform the Commission and the other Member States thereof.

9. Article 11 of Directive 93/42 is entitled 'Conformity assessment procedures'. In so far as relevant to Class III medical devices, it provides that a manufacturer, in order to affix the CE marking, may either:

(a) follow the procedure relating to the EC declaration of conformity set out in Annex II (full quality assurance); or

(b) follow the procedure relating to the EC type-examination set out in Annex III, coupled with:

(i) the procedure relating to the EC verification set out in Annex IV;

or

(ii) the procedure relating to the EC declaration of conformity set out in Annex V (production quality assurance).

10. Article 16 of Directive 93/42 is entitled 'Notified bodies'. Under paragraph 6, where a notified body finds, inter alia, that relevant requirements of the directive have not been met or are no longer met by the manufacturer, it is, taking account of the principle of proportionality, to suspend or withdraw the certificate issued or place any restrictions on it unless compliance with such requirements is ensured

by the implementation of appropriate corrective measures by the manufacturer. In the case of suspension or withdrawal of the certificate or of any restriction placed on it or in cases where an intervention of the competent authority may become necessary, the notified body is to inform its competent authority accordingly. The Member State must inform the other Member States and the Commission.

11. Article 17(1) of Directive 93/42 provides in particular that medical devices which are considered to meet the essential requirements referred to in Article 3 must bear the CE marking of conformity when they are placed on the market.

12. Annex II to Directive 93/42 is entitled 'EC Declaration of Conformity (Full Quality Assurance System)'. So far as relevant to the case in the main proceedings, it provides that:

— the manufacturer is to ensure application of the approved quality system for the design, manufacture and final inspection of the products concerned and to be subject to audit and surveillance (section 1);

— a manufacturer who fulfils the obligations imposed by section 1 is to draw up, and keep, a written declaration of conformity in respect of the products concerned and to affix the CE marking in accordance with Article 17 (section 2);

— the manufacturer is to lodge an application for assessment of his quality system with a notified body, incorporating undertakings on his part (i) to fulfil the obligations imposed by the approved quality system, (ii) to keep that system adequate and efficacious and (iii) to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective action (section 3.1);

— application of the quality system must ensure that the products conform to the provisions of the directive which apply to them at every stage from design to final inspection; the quality system is to include an adequate description of (i) the methods of monitoring the efficient operation of the quality system and in particular the ability to achieve the desired quality of design and of product, including control of products which fail to conform and (ii) the procedures for monitoring and verifying the design of the products (section 3.2);

— the notified body is to audit the quality system to determine whether it meets the requirements referred to in section 3.2; that procedure must include an inspection on the manufacturer's premises (section 3.3);

— the manufacturer is to lodge an application with the notified body for examination of the design dossier relating to the product, to be followed, if the product conforms to the relevant provisions of the directive, by the issuing by the notified body of an EC design-examination certificate (section 4);

— 'the aim of surveillance is to ensure that the manufacturer duly fulfils the obligations imposed by the approved quality system' (section 5.1); in that connection, the manufacturer must authorise the notified body to carry out all the necessary inspections and supply it with all relevant information, in particular (i) the documentation on the quality system, (ii) the data stipulated in the part of the quality system relating to design and (iii) the data stipulated in the part of the quality system relating to manufacture (section 5.2);

— as part of the surveillance procedure, the notified body must periodically carry out appropriate inspections and assessments to make sure that the manufacturer applies the approved quality system and must supply the manufacturer with an assessment report (section 5.3);

— in addition, the notified body may pay unannounced visits to the manufacturer; at the time of such visits, the notified body may, where necessary, carry out or ask for tests in order to check that the quality system is working properly (section 5.4).

13. Annex XI to Directive 93/42 lays down a number of criteria to be met for the designation of notified bodies. It provides, in particular, that their impartiality must be guaranteed (section 5). Section 6 states that:

'The body must take out civil liability insurance, unless liability is assumed by the State under domestic legislation or the Member State itself carries out the inspections directly.

…'

Directive 2003/12

14. By virtue of Article 1 of Directive 2003/12,[4] 'in order to ensure the highest possible level of safety for breast implants'[5] the latter were classified as medical devices falling within Class III. That directive came into force with effect from 1 September 2003. Breast implants placed on the market prior to that date were to be subject to a conformity reassessment procedure as Class III medical devices before 1 March 2004.[6]

National law

15. Directive 93/42 was transposed into German law by the Medizinproduktegesetz (the Law on medical devices; 'the MPG'), in conjunction with the Medizinprodukteverordnung (the Order on medical devices; 'the MPV').

16. In accordance with Paragraph 6(2) of the MPG, Class III medical devices may be placed on the market in Germany only if, inter alia, a conformity assessment procedure has been carried out in accordance with Paragraph 37(1) of the MPG and Paragraph 7(1), point 1, of the MPV in conjunction with Annex II to Directive 93/42.

17. By virtue of the Bürgerliches Gesetzbuch (German Civil Code; 'the BGB'), and in particular Paragraphs 157 and 242 thereof, as interpreted in national case-law, a person who is not a party to a contract may, in certain circumstances, benefit from the duties imposed on a party thereto by that contract to exercise all due diligence and to take all due care. Under Paragraph 823(2) of the BGB, read in conjunction with the measures referred to in point 16 above, liability in tort or delict may arise by reason of the breach of a rule conferring legal protection.

Facts, procedure and the question referred for a preliminary ruling

18. On 1 December 2008, the applicant, Ms Elisabeth Schmitt, had silicone breast implants fitted in Germany. These were manufactured by an undertaking resident in France, which has since become insolvent.[7]

4 — Commission Directive 2003/12/EC of 3 February 2003 on the reclassification of breast implants in the framework of Directive 93/42 (OJ 2003 L 28, p. 43).

5 — Recital 3.

6 — Articles 2 and 3.

7 — The breast implants in question were manufactured by Poly Implant Prothèse (PIP).

19. The defendant, TÜV Rheinland LGA Products GmbH ('TÜV Rheinland'), was at all relevant times the notified body appointed by the manufacturer for the purposes of Directive 93/42. It is common ground that prior to 1 December 2008, as part of its duties under its contract with the manufacturer, the defendant had paid announced visits to the manufacturer's premises in November 1998, January 2000, November 2000, February 2001, December 2001, November 2003, November 2004 and March 2006. It did not inspect the business records or order that any of the products be examined; nor did it pay any unannounced visits.

20. In 2010, the competent French authority found that low-grade industrial silicone had been used to manufacture the breast implants in breach of the applicable quality standard. As a result and following on medical advice, the applicant had her implants removed in 2012. She has brought proceedings before the courts in Germany, seeking to obtain EUR 40 000 from the defendant by way of compensation for non-material damage and a declaration that the defendant is liable for any material damage that may arise in the future. She argues that an inspection of the delivery notes and invoices in the manufacturer's possession would have made it clear to the defendant that the approved (medical grade) silicone had not been used.

21. The action was unsuccessful before the lower courts. Ms Schmitt has now brought an appeal on a point of law before the Bundesgerichtshof (Federal Court of Justice), in which she maintains the heads of claim forming the basis of her original action.

22. That court is uncertain as to the interpretation of EU law for the resolution of the dispute in the main proceedings. It has accordingly referred the following questions to the Court of Justice pursuant to Article 267 TFEU:

'(1) Is it the purpose and intention of [Directive 93/42] that, in the case of Class III medical devices, the notified body responsible for auditing the quality system, examining the design of the product and surveillance acts in order to protect all potential patients and may therefore, in the event of a culpable infringement of an obligation, have direct and unrestricted liability towards the patients concerned?

(2) Does it follow from [points 3.3, 4.3, 5.3 and 5.4] of Annex II to [Directive 93/42] that, in the case of Class III medical devices, the notified body responsible for auditing the quality system, examining the design of the product and surveillance is subject to a general obligation to examine devices, or at least to examine them where there is due cause?

(3) Does it follow from the aforementioned points of Annex II to [Directive 93/42] that, in the case of Class III medical devices, the notified body responsible for auditing the quality system, examining the design of the product and surveillance is subject to a general obligation to examine the manufacturer's business records and/or to carry out unannounced inspections, or at least to do so where there is due cause?'

23. Written observations have been submitted by Ms Schmitt, TÜV Rheinland, the French and German Governments, Ireland and the Commission. At the hearing on 26 May 2016, Ms Schmitt, TÜV Rheinland, the German Government, Ireland and the Commission presented oral argument.

Analysis

Preliminary remarks

The New Approach

24. The New Approach finds its origins in the Court's judgment in the *Cassis de Dijon* case.[8] In holding that Member States could justify forbidding or restricting the marketing of products from other Member States on the basis only of non-conformity with what were termed in that judgment 'mandatory requirements'[9] (and are termed 'essential requirements' in the subsequent legislation), the Court opened the door to a reflection on how goods could best be marketed within the European Community in full respect of the rules governing the free movement of goods whilst at the same time ensuring that the needs of product safety could be met. The initial result was Council Resolution of 7 May 1985 on a new approach to technical harmonisation and standards.[10] That resolution provided for legislative harmonisation to be linked to the essential requirements that products to be placed on the Community market must meet in order to benefit from free movement within the Member States. In order to do that, it was necessary to establish technical specifications for the relevant products, to be laid down in harmonised standards which could be applied alongside the legislation. Products manufactured in accordance with those standards were to benefit from a presumption of conformity with those essential requirements.

25. In order for that system to work and for trust to be established between the Member States, the harmonised standards in question needed to offer a guaranteed level of protection. To that end, an appropriate conformity assessment policy had to be developed. This consisted of a series of modules, to be selected by the legislature having regard to the nature of the product in question and the risks associated with it. Where the level of risk associated with the product in question was high, the module would involve, as an essential element, the participation of an independent entity, known as a 'notified body', which would have the duty, inter alia, of assessing the conformity of the product with the legislative requirements. Those modules were first described in Decision 90/683,[11] which was subsequently updated and replaced by Decision 93/465.[12] The provisions of Module H (entitled 'full quality assurance') set out in the annexes to each of those decisions closely resemble those of Annex II to Directive 93/42.[13]

26. The Court has held that Directive 93/42 must reconcile the free movement of medical devices with the protection of patients' health.[14] It has also held that the aim of the directive is not only the protection of health *stricto sensu* but also the safety of persons.[15]

8 — Judgment of 20 February 1979, *Rewe-Zentral*, 120/78, EU:C:1979:42. For a full description of the context in which the New Approach was adopted, its essential features and potential future reforms, see Commission Notice of 5 April 2016, commonly referred to as the 'Blue Guide' on the implementation of EU product rules 2016, C(2016) 1958 final.

9 — See paragraph 8 of the judgment.

10 — OJ 1985 C 136, p. 1.

11 — Council Decision 90/683/EEC of 13 December 1990 concerning the modules for the various phases of the conformity assessment procedures which are intended to be used in the technical harmonisation directives (OJ 1990 L 380, p. 13).

12 — Council Decision 93/465/EEC of 22 July 1993 concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the CE conformity marking, which are intended to be used in the technical harmonisation directives (OJ 1993 L 220, p. 23).

13 — See point 12 above.

14 — See judgments of 14 June 2007, *Medipac — Kazantzidis*, C-6/05, EU:C:2007:337, paragraphs 51 and 52, and of 22 November 2012, *Brain Products*, C-219/11, EU:C:2012:742, paragraphs 27 and 28.

15 — See, in that regard, judgment of 19 November 2009, *Nordiska Dental*, C-288/08, EU:C:2009:718, paragraph 29,

Applicability of Directive 93/42 to the case in the main proceedings

27. The referring court seeks guidance on the interpretation of Directive 93/42 to the case in the main proceedings, with particular reference to the potential liability of TÜV Rheinland to Ms Schmitt. It does not offer guidance as to the precise legal status of that entity, but it seems clear that the latter is not, as such, a State body or an emanation of the State. [16] It follows that there can be no question of the terms of that directive being directly enforceable against TÜV Rheinland, since the relationship between that body and Ms Schmitt is 'horizontal' [17] and not 'vertical'. [18] This Court can, however, offer guidance to the referring court, as that court rightly observes in its order for reference, as to the proper interpretation of Directive 93/42, in the light of its wording and purpose, thereby enabling the referring court so far as possible to interpret national law in conformity with EU law. [19]

Question 1

28. By Question 1, the referring court asks whether the purpose and intention of Directive 93/42 is that a notified body carrying out its functions in respect of Class III medical devices does so in order to protect all potential patients and may accordingly, in the event of a culpable failure to comply with its obligations, have direct and unrestricted liability towards the patients concerned. I have already referred to the fact that the Court has held that the aim of the directive includes the safety of persons. [20]

29. The referring court states in the order for reference that, from the point of view of German law, the decision to be given on the dispute in the main proceedings depends crucially on the purpose served by the inclusion of a notified body in the conformity assessment procedure under Directive 93/42. Although it does not explain precisely what it has in mind in using the expression 'direct and unrestricted liability', it does devote some time to setting out the rules under national law which may lead to TÜV Rheinland incurring liability either under the law of tort or delict, on the one hand, or under contract law, on the other hand, to a third party, such as (in this case) Ms Schmitt.

30. Since the interpretation of national law is a matter for the referring court alone, the issues concerning the precise classification of the liability, if any, that may arise in a domestic context cannot be addressed in this Opinion. It is, however, open to the Court to offer guidance as to the circumstances in which Directive 93/42 may contemplate liability being imposed on a notified body and that is what I shall focus on below.

31. In support of the argument that no liability can attach to a notified body in the present case, TÜV Rheinland has emphasised the liability imposed on the *manufacturer* of the devices concerned. It does so in reliance not only on the wording of Directive 93/42 but also on the scheme and general purpose of Directive 85/374 concerning liability for defective products. [21]

16 — See, as regards the test to be applied, judgment of 12 July 1990, *Foster and Others*, C-188/89, EU:C:1990:313, and in particular paragraphs 18 and 20. See also Case C-413/15 *Farrell* v *Whitley* (pending before the Court), where the Supreme Court, Ireland, seeks further clarification as to the precise nature of this test and whether it is disjunctive or cumulative.

17 — That is to say, the relationship is between private parties and does not involve the State.

18 — That is to say, a relationship in which one of the parties is private and the other is the State or an emanation of the State.

19 — See in that regard, inter alia, judgments of 13 November 1990, *Marleasing*, C-106/89, EU:C:1990:395, paragraph 8; of 5 October 2004, *Pfeiffer and Others*, C-397/01 to C-403/01, EU:C:2004:584, paragraph 115; and of 4 July 2006, *Adeneler and Others*, C-212/04, EU:C:2006:443, paragraph 108 et seq.

20 — See point 26 above.

21 — Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products (OJ 1985 L 210, p. 29).

32. The second recital of Directive 85/374 states that liability without fault on the producer's part is the sole means of adequately solving the problem of a fair apportionment of the risks inherent in modern technological production. To that end, Article 1 imposes liability for damage caused by a defective product on its producer. By virtue of Article 3(1), the producer will in most cases be the manufacturer. The Court has held that attempts under national law to extend the liability to suppliers of a product will, prima facie, be in breach of the directive's aim of achieving complete harmonisation in respect of the matters regulated by it.[22] At the same time, however, it has held that the scope of the directive, and hence of the complete harmonisation which it seeks to provide, is limited to the area of no-fault liability. It follows that Directive 85/374 is to be interpreted as not precluding the application of other systems of contractual or non-contractual liability based on other grounds, such as fault.[23] Since it is the question of fault that lies at the heart of the present order for reference, I draw no useful guidance from Directive 85/374.

33. Turning back, therefore, to Directive 93/42, it is clear that that directive imposes primary responsibility for compliance of the product on the manufacturer. Thus, sections 1 and 2 of Annex II provide that it is the manufacturer who is to ensure application of the quality system approved for the design, manufacture and final inspection of the products concerned and to draw up a written declaration of conformity.

34. Plainly, however, that directive does not limit the obligations as to product safety to the manufacturer alone. It also imposes a number of duties on Member States. In particular: (i) Article 2 requires the Member States to take all necessary steps to ensure that devices may be placed on the market and/or put into service only if they comply with the requirements laid down in the directive, (ii) Article 8(1) provides for Member States to take interim measures, inter alia, to withdraw devices which may compromise the health and/or safety of users from the market and to inform the Commission of those measures and (iii) Article 10 lays down certain duties as to the recording and evaluation of information brought to Member States' knowledge, with a concomitant obligation to inform the Commission in appropriate cases. Where the latter receives a notification under Article 8(1), Article 8(2) requires it to consult the parties concerned as soon as possible and, where it finds that the measures taken by the Member State are justified, it must immediately take the further steps listed in the first indent.

35. The directive is silent as regards the imposition of liability on notified bodies, although the requirement under section 6 of Annex XI that they take out civil liability insurance makes it clear that liability for something is contemplated. May the notified bodies be liable to users of those devices in the event of a culpable failure on their part to fulfil their duties?

36. If such liability does exist, it may be necessary to define its parameters closely.

37. In support of its argument that liability cannot — at least as regards users in Ms Schmitt's position — be imposed on notified bodies, the German Government draws attention to the Court's judgment in *Yonemoto*.[24] That case required the Court to consider the liability of an importer of machinery bearing the CE marking that had been manufactured in one Member State into another Member State. The structure of the applicable EU legislation,[25] while not identical to that of Directive 93/42, was similar. The Court found that national provisions requiring an importer in that position to ensure that such machinery meets the essential health and safety requirements laid down by that

22 — See, for example, judgment of 25 April 2002, *Commission* v *France*, C-52/00, EU:C:2002:252, paragraphs 24, 40 and 41.

23 — See, inter alia, judgment of 10 January 2006, *Skov and Bilka*, C-402/03, EU:C:2006:6, paragraphs 46 to 48. See also Mak, V., 'The Degree of Harmonisation in the Proposed Consumer Rights Directive: A Review in Light of Liability for Products' in *Modernising and Harmonising Consumer Contract Law*, Howells, G., and Schulze, R., Sellier, European Law Publishers, Munich, 2009, p. 307 et seq.

24 — Judgment of 8 September 2005, *Yonemoto*, C-40/04, EU:C:2005:519.

25 — The case concerned Directive 98/37/EC of the European Parliament and of the Council of 22 June 1998 on the approximation of the laws of the Member States relating to machinery (OJ 1998 L 207, p. 1). That directive was also adopted under the New Approach (see recitals 9 and 23).

directive were not permissible, since it would be contrary to the scheme of the legislation to increase the number of persons who could be responsible for the conformity of machinery. However, the Court also noted that the directive allowed for certain obligations to be imposed on such an importer. It followed that the legislation of a Member State might validly impose obligations on an importer to comply with obligations under national law having equivalent effect.[26] The Court found, in other words, that national legislation imposing some form of blanket liability on a party other than the manufacturer was unacceptable but, by contrast, that that legislation could impose liability limited to the specific obligations which the legislation laid down.

38. Thus, I do not see that that judgment can be used to support the German Government's position;[27] rather, I see it as establishing, at least in part, the contrary. If it is competent for a Member State to impose obligations on an importer from one Member State to another — and thus a party occupying a comparatively minor role — as regards its obligations under a New Approach directive, it must *a fortiori* be competent for it to do so as regards a notified body. The question then arises as to what the consequences as regards third parties suffering loss or injury as a result of a breach of those obligations may be. The Court in *Yonemoto* (C-40/04, EU:C:2005:519) went on to note that the directive did not impose any specific obligations on the Member States as regards the system of civil and criminal penalties that national law might enact. It observed, however, that that did not mean that national provisions imposing liabilities for infringements of legislation implementing that directive were incompatible with the latter. Those provisions would, in effect, be valid provided the principles of equivalence and effectiveness were respected.[28] Since the national court's questions in that case concerned the issue of criminal liability, the Court concentrated on that point in giving its answers. But those principles can plainly apply to civil remedies in respect of breaches of obligations arising under EU law as well.[29]

39. Given the crucial role played by notified bodies in the procedure leading to the placing on the market of medical devices governed by Directive 93/42 and bearing in mind, in particular, the high level of protection to patients and users that that directive aims to provide[30] and the risks associated with the devices in relation to which they are required to carry out their examination, it seems to me entirely appropriate that those bodies should in principle be capable of bearing liability under national law to those patients and users for a culpable failure to fulfil their obligations thereunder, provided always that the principles of equivalence and effectiveness are respected. That will be a matter for the national court to determine.

40. I therefore conclude that the answer to Question 1 should be that it is the purpose and intention of Directive 93/42 that, in the case of Class III medical devices, the notified body responsible for auditing the quality system, examining the design of the product and surveillance acts in order to protect all potential patients and may therefore, in the event of a culpable infringement of an obligation under that directive, be liable to the patients and users concerned, provided that the principles of equivalence and effectiveness are respected. The last of these aspects will be a matter for the national court to determine.

26 — See paragraphs 44, 46 and 48 of the judgment.

27 — Nor, for the sake of completeness, do I draw any useful guidance from the Court's judgment of 12 October 2004, *Paul and Others*, C-222/02, EU:C:2004:606, where it held that, whilst the objectives of the EU legislation then applicable in relation to deposit-guarantee schemes included the protection of depositors, it conferred no rights on those depositors in the event of defective supervision on the part of the competent national authorities (see paragraphs 38 and 40). The scope and content of the legislation is simply too different for any useful parallel to be drawn.

28 — See paragraphs 56 to 59 of the judgment.

29 — See, inter alia, judgment of 6 March 2007, *Placanica and Others*, C-338/04, C-359/04 and C-360/04, EU:C:2007:133, paragraph 63.

30 — See, in that regard, point 26 above.

Questions 2 and 3

41. By Questions 2 and 3, which should be considered together, the referring court seeks clarification as to the duties of a notified body, acting in the context of Annex II to Directive 93/42, as regards (i) examining devices and (ii) examining the manufacturer's business records and/or carrying out unannounced inspections.

42. Those duties may be either general in nature, that is to say, that there is an obligation to perform them on a regular basis and without due cause of any kind; or they may be particular, that is to say, that the notified body is required to undertake them only where there is a reason for it to do so.

43. I shall address the former before turning to the latter.

Preliminary observations

44. Before I do so, however, I would like to offer three observations. The first is that notified bodies must satisfy stringent requirements, not only as to their independence but also as to their expertise. This is evidenced, inter alia, by section 2 of Annex XI to Directive 93/42, which provides that those bodies must act with 'the highest degree of professional integrity and the requisite competence in the field of medical devices'. It would run entirely counter to that requirement for this Court to lay down requirements that are unnecessarily prescriptive as to the manner of their operations. They must be allowed an appropriate degree of discretion in that regard.

45. The second is that the role of notified bodies is primarily a scientific one. They are involved in the procedures laid down in Directive 93/42 for reasons of product safety. They are not in any way law enforcement bodies and should not be regarded as having duties concomitant with that office.

46. The third is that, as I stated in my Opinion in *Medipac- Kazantzidis*, CE marking does not make medical devices infallible.[31] The aim which Directive 93/42 sets out to achieve is a high level of protection, not an absolute one.[32] The duties of the notified bodies must be seen in that context.

General obligations imposed on a notified body

47. Annex II to Directive 93/42 divides the duties of a notified body into three categories. The first comprises the obligations as to audit of the manufacturer's quality system set out in section 3.3. The purpose of that audit is to ensure that the system in question meets the requirements imposed on the manufacturer in section 3.2. Whilst by its nature such an exercise must essentially be a documentary and procedural one, it is worth noting that the notified body must also carry out an inspection on the manufacturer's premises as part of that process. But given the preliminary stage at which those duties are to be undertaken, the notified body cannot be under a general obligation as to the inspection of individual devices, examination of the manufacturer's business records or the carrying-out of unannounced inspections in this context.

31 — See my Opinion in *Medipac-Kazantzidis*, C-6/05, EU:C:2006:724, point 92.

32 — Indeed, Directive 85/374 proceeds from the premiss that, however good the level of supervision and scrutiny of the production process, defective products will occasionally be manufactured and find their way onto the market, to the detriment of consumers. See, in that regard, recital 7, which states that fair apportionment of risk between the injured person and the producer implies that the producer should be able to free himself from liability if he furnishes proof as to the existence of 'certain exonerating circumstances'.

48. Section 4.3 of Annex II requires the notified body to examine the manufacturer's design dossier related to products which he plans to manufacture. If the body considers that the product conforms to the requisite provisions of the directive, it is to issue an EC design-examination certificate. Once again, these requirements arise at a preliminary stage and the notified body cannot therefore be under a general obligation to carry out the tasks referred to in point 47 above.

49. Lastly, section 5 of Annex II imposes a series of obligations on notified bodies under the category of 'surveillance',[33] the aim of which is, according to section 5.1, 'to ensure that the manufacturer duly fulfils the obligations imposed by the approved quality system'. By virtue of section 5.3, the notified body is to carry out appropriate inspections and assessments on a periodic basis in order to make sure that the manufacturer applies the approved quality system. That is supplemented by section 5.4, according to which that body *may*, in addition, pay unannounced visits to the manufacturer. As part of that surveillance by the notified body, the manufacturer is under a duty under section 5.2 to authorise that body to carry out all the necessary inspections and supply it with all relevant information, including in particular the documentation on the quality system and certain data stipulated in that system. Where that body pays an unannounced visit, section 5.4 provides that it may, where necessary, carry out or ask for tests in order to check that the quality system is working properly.

50. Plainly, the question whether there is a general obligation to inspect devices, examine the manufacturer's business records or carry out unannounced inspections is capable of being considerably more relevant under this section of Annex II than it is in relation to sections 3 or 4.

51. It is important, however, to consider the context in which a notified body carries out its duties. To emphasise the cooperative aspect of the relationship between the notified body and the manufacturer, as TÜV Rheinland does in its observations, is in my view unduly simplistic. That fails to take into account the obligations as to independence and surveillance (including powers of inquiry) which Directive 93/42 lays down. That said, it seems to me that, in the normal course, a manufacturer can probably be assumed to be operating in accordance with its approved quality system and producing devices complying with the product design and that a notified body may therefore proceed upon that assumption. It is therefore under no general obligation to inspect devices, examine the manufacturer's business records or carry out unannounced inspections.

Particular obligations imposed on a notified body

52. As I mentioned in point 46 above, the system put in place by the CE marking system does not amount to a guarantee of infallibility. That, indeed, is why market surveillance on a continuing basis is necessary.[34] Whilst it is no doubt possible to envisage a wide number of potential situations of product failure, I would isolate three in particular for the sake of discussion: (i) a failure which could be foreseen by no one and for which no party could, on any realistic basis, be held responsible, (ii) a genuine, and entirely honest oversight on the manufacturer's part which could nonetheless have been isolated with the involvement of a third party having sufficient knowledge at a scientific level and suitable familiarity with the procedures and processes involved and (iii) deceit or fraud on the manufacturer's part.

33 — 'Market surveillance' is a task primarily entrusted to the Member States with a view to ensuring that unsafe products or products which otherwise do not conform to applicable requirements set out in Union harmonisation legislation are identified and kept or taken off the market and unscrupulous (or even criminal) operators punished: see Commission Notice C(2016) 1958 final referred to in footnote 8 above and, for example, as regards the duties imposed on Member States, point 34 above. That is to be distinguished from the more specific duties as to 'surveillance' imposed on a notified body pursuant to section 5 of Annex II to Directive 93/42.

34 — See my Opinion in *Medipac-Kazantzidis*, C-6/05, EU:C:2006:724, point 92. See also footnote 33 above.

53. As regards the first of these possibilities, once it is clear that the failure has arisen, the notified body will be under a duty, by virtue of Article 16(6) of Directive 93/42 and taking account of the proportionality principle, to suspend or withdraw its certification or place restrictions on it until compliance has been ensured or appropriate corrective measures have been put in place by the manufacturer. The notified body must also inform its competent national authority where the certificate is withdrawn or any restrictions are placed on it or otherwise where the intervention of that authority may become necessary.

54. Concerning the second and third of those possibilities, I concluded in point 51 above that a notified body is not under any form of general obligation as to the tasks there referred to. However, it seems to me that, as part of its general duty of diligence, a notified body is under a duty to be alert to the fact that either of those possibilities may arise in any given case. If, therefore, it is put on notice, whether as a result of information arising out of its own inspections and assessments or otherwise, it will be under a duty to act. Article 16(6) will of course apply in all cases.

55. With respect to the second possibility, it is probable that since the oversight was an honest one the manufacturer will provide all assistance to the notified body that is necessary to enable that body to establish the position and to take all necessary measures to rectify the situation.

56. If and to the extent, however, that such assistance is not forthcoming or in cases of deceit or fraud on the manufacturer's part (the third possibility), the precise nature of the powers available to a notified body will be placed in sharp focus. In that context and as I mentioned in point 45 above, it is necessary to bear in mind that notified bodies do not have a law enforcement role. Their duty is to establish whether or not their certification may still stand. [35]

57. Given the high-risk nature of the Class III medical devices associated with that certification, it seems to me that those bodies are under an obligation to take all necessary steps in that context. Having regard to their scientific expertise, how, exactly, those bodies choose to act and what precise steps they take in such a situation seems to me to be a matter lying very much within their discretion provided that they exercise all due care and diligence at all times. [36] Here, it should be noted that the obligations placed on the manufacturer under section 5.2 of Annex II to provide notified bodies with certain documentation and data [37] are illustrative and not exhaustive. The overriding duty imposed on manufacturers by that provision is to authorise the notified body to carry out *all* the necessary inspections and to supply it with *all* relevant information. If, in that connection, a notified body considers that it is necessary to examine devices and/or to examine the manufacturer's business records, then the manufacturer is bound to allow it to do so. As to whether such a body is under a duty to carry out an examination in that regard, no precise guidelines can be laid down by this Court. That will be a matter to be assessed by the national court on a case-by-case analysis. The question will be: what would a notified body acting with all due care and diligence have done in the circumstances in question? The same applies to the question whether the notified body should have carried out unannounced inspections. [38]

58. I should add for the sake of good order that, although the referring court's questions refer to the role of notified bodies acting in relation to Class III medical devices pursuant to Annex II to Directive 93/42, analogous rules and principles will apply where such bodies act in relation to those devices under the alternative procedures laid down under Article 11(1)(b) of that directive, that is to say, Annex III, coupled with either Annex IV or Annex V.

35 — See section 4 of Annex II to Directive 93/42, referred to in point 12 above.

36 — See point 44 above.

37 — See point 49 above.

38 — The referring court uses the expression 'unannounced inspections' ('unangemeldete Inspektionen' in the German original), whilst section 5.4 of Annex II to Directive 93/42 refers to 'unannounced visits' ('unangemeldete Besichtigungen' in the German-language version of the directive). Since the purpose of such visits would, in nearly every case, be to carry out inspections, I draw nothing from that choice of words.

59. I therefore conclude that the answer to Questions 2 and 3 should be that Annex II to Directive 93/42 should be interpreted as meaning that, in the case of Class III medical devices, the notified body responsible for auditing the quality system, examining the design of the product and surveillance is under a duty to act with all due care and diligence. Where it is on notice that a medical device may be defective, that duty will require it to exercise the powers available to it under that annex in order to determine whether its certification of the device in question may stand. The precise nature and extent of that duty will fall to be determined on a case-by-case basis, and will be a matter for the national court to determine.

Temporal effect of the Court's ruling

60. Ireland has requested that, in the event that this Court should hold that the referring court's questions should be answered in the affirmative, it should limit the temporal effect of its ruling *ex nunc* to the date of its judgment. It argues that the interests of legal certainty so require, and that, in particular, there would be a risk of serious economic repercussions were the position to be otherwise. It is not difficult to see the force of that argument. In particular, it is possible that the insurance cover taken out by some, or possibly all, of the notified bodies concerned under section 6 of Annex XI to Directive 93/42 may not extend to liability of that nature. I therefore agree that the effects of any judgment to follow hereon which finds that notified bodies may incur liability arising out of a failure to meet their duties under that directive should be limited in the manner which Ireland proposes. Since, however, the notified bodies will not be exposed to financial risk to the extent that those liabilities are in fact already the subject of insurance cover, I would limit any such temporal limitation to liability incurred by a notified body which is not already subject to insurance cover by virtue of section 6 of that annex.

Conclusion

61. I therefore suggest that the Court should answer the questions referred by the Bundesgerichtshof (Federal Court of Justice, Germany) as follows:

(1) It is the purpose and intention of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices that, in the case of Class III medical devices, the notified body responsible for auditing the quality system, examining the design of the product and surveillance acts in order to protect all potential patients and may therefore, in the event of a culpable infringement of an obligation under that directive, be liable to the patients and users concerned, provided that the principles of equivalence and effectiveness are respected. The last of these aspects will be a matter for the national court to determine.

(2) Annex II to Directive 93/42 should be interpreted as meaning that, in the case of Class III medical devices, the notified body responsible for auditing the quality system, examining the design of the product and surveillance is under a duty to act with all due care and diligence. Where it is on notice that a medical device may be defective, that duty will require it to exercise the powers available to it under that annex in order to determine whether its certification of the device in question may stand. The precise nature and extent of that duty will fall to be determined on a case-by-case basis, and will be a matter for the national court to determine.

(3) Directive 93/42 should not be interpreted as imposing liability on a notified body to a patient or user of a medical device where that liability arose before the date of the judgment to follow hereon, save and to the extent that the liability in question may already be the subject of insurance cover taken out by the notified body concerned.