



Reports of Cases

OPINION OF ADVOCATE GENERAL
MENGOZZI
delivered on 15 May 2012¹

Case C-219/11

Brain Products GmbH
v
BioSemi VOF and Others

(Reference for a preliminary ruling from the Bundesgerichtshof (Germany))

(Free movement of goods — Directive 93/42/EEC — Concept of ‘medical device’ — Product intended to be used for a non-medical purpose)

I – Introduction

1. The creation of the CE marking, which identifies in a number of specific sectors the products which meet the basic requirements provided for under European Union law, was a milestone in the establishment of the single market. It has made it possible for a very high number of products to circulate freely, without Member States being able, by means of national legislation, to impede the sale of those products.

2. One of the sectors in which the European Union introduced the CE marking system was the medical devices sector, which is governed by Directive 93/42/EEC.² In the present case, the Court is called upon to clarify the precise scope of that directive and, more specifically, to determine whether it encompasses products which, although they meet one of the definitions set out in Directive 93/42, are not intended to be used for a medical purpose.

II – Legal context

A – General considerations

3. The European Union’s approach to the harmonisation of products which can be traded in the single market has evolved over time. Initially, the general approach was to lay down very detailed rules setting out a large number of technical requirements in meticulous detail. However, rules laid down in such detail involve significant disadvantages: they are difficult to put into effect and are likely to prove incapable of keeping pace with technological developments.

¹ — Original language: Italian.

² — Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ 1993 L 169, p. 1), as amended.

4. Consequently, from the mid-1980s, the legislature decided to take a different approach to technical harmonisation. The advent of the ‘new approach’, as the new strategy was described, took the form of a resolution adopted by the Council on 7 May 1985.³ That document clearly sets out the two essential elements of the new approach: (a) legislative harmonisation covering only the essential requirements and (b) the harmonised (technical) standards playing a central role.

5. Under the ‘new approach’, the harmonisation of legislation is confined to the ‘essential requirements’ of products, which are set out in detail in a series of sectoral directives. The fact that a particular product bears the CE marking is a sign that it satisfies those essential requirements. In general, responsibility for attesting compliance with the essential requirements lies with the manufacturer.

6. Products which meet the ‘harmonised standards’ are presumed to be in conformity with the essential requirements. The harmonised standards are technical standards which are drawn up, at national and European Union level, by the bodies responsible for industrial standardisation. Compliance with the harmonised standards is not mandatory, but strongly encouraged by the legislature, specifically by means of the presumption of conformity. It is possible for a manufacturer to demonstrate that the essential requirements have been met without adhering to the harmonised standards; in most cases, however, this is an unnecessary complication. In practice, products are usually manufactured in accordance with the harmonised standards.

7. There are rather a lot of ‘new approach’ directives and they cover a broad range of products, ranging from toys⁴ to explosives,⁵ and from radio equipment⁶ to lifts.⁷ If a product falls within the scope of one (or more) of the ‘new approach’ directives, it *must* comply with the essential requirements laid down in the directive or directives and, in consequence, must bear the CE marking.

B – Directive 93/42

8. In the present case, as I stated above, the point of reference is the directive governing medical devices.

9. The following definition of ‘medical device’ is set out in Article 1(2)(a) of Directive 93/42:

‘any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,

3 — OJ 1985 C 136, p. 1.

4 — Council Directive 88/378/EEC of 3 May 1988 on the approximation of the laws of the Member States concerning the safety of toys (OJ 1988 L 187, p. 1).

5 — Council Directive 93/15/EEC of 5 April 1993 on the harmonisation of the provisions relating to the placing on the market and supervision of explosives for civil uses (OJ 1993 L 121, p. 20).

6 — Directive 1999/5/EC of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity (OJ 1995 L 91, p. 10).

7 — Directive 95/16/EC of the European Parliament and of the Council of 29 June 1995 on the approximation of the laws of the Member States relating to lifts (OJ 1995 L 213, p. 1).

— control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means ...’

10. Article 2 of Directive 93/42, entitled ‘Placing on the market and putting into service’, makes it clear that products covered by the definition under Article 1(2)(a) may be placed on the market only if they comply with the requirements laid down in that directive. Pursuant to Article 3 of Directive 93/42, this means, in essence, that the products must meet the ‘essential requirements’ set out in Annex I.

11. Article 5 of Directive 93/42, entitled ‘Reference to standards’, lays down in the following terms the principle of the presumption of compliance in respect of products which meet the harmonised standards:

‘Member States shall presume compliance with the essential requirements referred to in Article 3 in respect of devices which are in conformity with the relevant national standards adopted pursuant to the harmonised standards the references of which have been published in the *Official Journal of the European Communities*; ...’

12. Lastly, Article 17 of Directive 93/42 provides that all products which meet the essential requirements must bear the CE marking of conformity.

13. The harmonised standards to which Article 5 of Directive 93/42 refers are published periodically in the Official Journal. The list of harmonised standards for medical devices was most recently published in August 2011.⁸

C – The Commission’s guidelines

14. The Commission regularly publishes guidelines on the interpretation of the ‘new approach’ directives, principally in order to provide guidance to the manufacturers of products potentially subject to the obligations laid down under European Union legislation. While the guidelines are not legally binding, it is expedient not to ignore their existence, in order at least to establish how the standards are interpreted in current practice.

15. As regards medical devices in particular, it is worth mentioning here a document (MEDDEV 2.1/1) published by the Commission in April 1994 and defining a number of key concepts contained in Directive 93/42.⁹ As far as the concept of ‘medical device’ is concerned, the Commission explicitly states in that document that ‘[m]edical devices are defined as articles *which are intended to be used for a medical purpose*’.¹⁰ The Commission goes on to state that the ‘medical purpose is assigned to a product by the manufacturer’.

8 — Commission communication in the framework of the implementation of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (Publication of titles and references of harmonised standards under the directive) (OJ 2011 C 242, p. 8).

9 — The document is available on the Commission’s website. At the date of this Opinion, the list of the guidelines relating to medical devices may be consulted at: http://ec.europa.eu/health/medical-devices/documents/guidelines/index_en.htm.

10 — Paragraph 1.1(b) of the document. Emphasis added, although, in the Commission’s text, the expression ‘medical purpose’ is underlined.

III – Facts and the question referred for a preliminary ruling

16. BioSemi, a company governed by Netherlands law, markets a product called ‘ActiveTwo’. This is a system capable of recording electrical signals from the human body and, more specifically, from the brain (EEG), the heart (ECG) and the muscles (EMG). Although measurements of that nature are frequently taken in a healthcare context (using electrocardiograms, electroencephalograms and so on), the product in question is not designed for the medical sector and the related promotional material explicitly states that it is not designed to be used for diagnosis and/or treatment. The primary users of ActiveTwo, which is modular and can therefore be configured to meet the needs of individual customers, are researchers carrying out investigations, particularly in the cognitive sciences.

17. The product does not bear the CE marking attesting to conformity with the directive on medical devices. That fact is currently made absolutely clear, *inter alia*, on the manufacturer’s website. The website also states that ActiveTwo is a product which is not designed for medical uses.

18. Brain Products – one of BioSemi’s competitors – brought an action against BioSemi on the basis that, regardless of its intended use, the system manufactured by BioSemi must be regarded as a medical device for the purposes of the directive and, accordingly, must be certified as such.

19. The action brought by Brain Products was dismissed at first and second instance and is now pending before the Bundesgerichtshof. By contrast with the lower courts, which did not consider conformity with Directive 93/42 necessary in the case of a device which is explicitly stated not to have been designed for medical use, the Bundesgerichtshof has doubts on the matter and has therefore referred the following question to the Court for a preliminary ruling:

‘Does a product which is intended by the manufacturer to be applied for human beings for the purpose of investigation of a physiological process constitute a medical device, within the terms of the third indent of Article 1(2)(a) of Directive 93/42/EEC, only in the case where it is intended for a medical purpose?’

IV – The question referred

20. It would appear that, until now, the interpretation of Directive 93/42 requested by the national court has never been a source of doubt, whether as regards practice in the Member States or as regards national case-law: the view has always been that the directive must be applied only to products which, in addition to falling within the definition of ‘medical devices’ set out in abstract terms in Article 1(2)(a) of Directive 93/42, are also intended to be used for medical purposes. That is the approach suggested by the Commission’s guidelines, and, according to the information available in the case-file, administrative practice in Germany and Netherlands reflects that view, too.

21. I must immediately point out, however, that the answer to the question referred is anything but straightforward. Ranged against the attractive simplicity of a literal interpretation of the third indent of Article 1(2)(a) of Directive 93/42 are a whole battery of arguments which, although appearing less significant when viewed in isolation, exert a considerable counterforce when taken together. While a reading of the third indent in isolation suggests that the product at issue should be categorised as a medical device, a systematic and teleological approach suggests, on the contrary, that a product of this type should not be regarded as falling within the scope of the directive and, accordingly, must not be certified as a medical device.

22. Let me say straightaway that, to my mind, the second group of arguments, considered collectively, is more convincing than a literal interpretation of the third indent. Consequently, for the reasons set out below, it is my view that a product like Biosemi’s ‘ActiveTwo’ should *not* be regarded as a medical device within the terms of Directive 93/42.

A – The literal interpretation

23. The literal interpretation of the third indent of Article 1(2)(a) of Directive 93/42 can be used to support the argument that a product like the product at issue must be subject to the rules on medical devices. It is clear that certain functions of the ‘ActiveTwo’ system can be defined as the ‘investigation ... of a physiological process’: ActiveTwo is an item of equipment which is able to record electrical signals emitted by the human body and, more specifically, by the heart, the brain and the muscles.

24. That interpretation is certainly very attractive, above all for its simplicity. There are many factors, however, which cannot be overlooked and which raise serious doubts as to the soundness of the literal approach.

25. First, the approach based on the teleological and systematic interpretations of Directive 93/42 is the opposite to that based on a literal interpretation: according to the teleological and systematic approach, only products which are intended to have a medical use are covered by the directive.

26. Secondly, the literal interpretation has disadvantages which should not be overlooked and which could give rise to wholly unexpected consequences.

27. I shall now consider separately the two aspects set out above, beginning with the systematic and teleological interpretation, and then moving on to the problems bound up with the literal interpretation.

28. It should be pointed out, moreover, that the issue of categorisation raised by the question referred can, in any event, arise only in relation to products which may be covered by the third indent of the definition. The use for medical purposes of the products covered by the first and second indents is, in fact, inherent in their very definition, which refers to activities involving diagnosis, prevention, treatment and so on. Products under the fourth indent, on the other hand, constitute – as we shall see shortly – an entirely special category so far as the intentions of the legislature are concerned, but nevertheless a category which can also, in any event, be regarded as having a ‘medical’ purpose.

B – The systematic and teleological interpretation

29. If we take a systematic and/or teleological approach to interpreting the directive, only those devices which are intended to be used for a medical purpose may be regarded as medical devices. There are many factors which support this view, and they may be summarised as follows.

1. The legislature’s choice of terminology

30. First of all, it should be pointed out that, beginning with its very title, Directive 93/42 refers to ‘medical’ devices. This is in itself a clear indication of the background against which the legislature drafted the rules: the idea was to define a reference framework capable of adequately protecting persons who, whether actively or passively, come into contact with the products in a medical setting.¹¹ Accordingly, it does not appear to be consistent with that basic idea, which informs the directive throughout, to bring within the scope of the directive products which are intended never to be used in a medical context. That is the position with a device like ‘ActiveTwo’: it is not used by the medical profession (or, at least, not by doctors in connection with the diagnosis and treatment of illness), and it is never used on patients but on volunteers (participants in clinical trials).

11 — See also, in that connection, the third and fifth recitals in the preamble which refer to safety and protection for ‘patients’, ‘users’ and ‘third parties’.

2. The references to ‘patients’

31. It is significant that the directive contains many references to ‘patients’. Had it been the legislature’s intention also to regulate products intended for spheres and purposes other than those typical of the medical sector, it would probably have employed different terminology to describe the ‘passive subjects’ of the use of the devices. There is in fact no way that those taking part in clinical trials in the field of the cognitive sciences can be described as ‘patients’.

32. On that point, I would observe that, in my view, no problem arises in connection with the fact that all products used for the ‘control of conception’ within the terms of the fourth indent of Article 1(2)(a) of Directive 93/42 are, without exception, categorised as medical devices. Even though the users of such products cannot generally be described as ‘patients’, there are a number of factors which should be borne in mind in this regard and which explain, I believe, the legislature’s decision to bring such products within the scope of the directive.

33. I am thinking, first, of the importance of at least some of those products for the prevention of sexually transmitted diseases, highlighted by the legislature in the eighteenth recital in the preamble to the directive, which states:

‘... in the fight against AIDS and in the light of the conclusions of the Council adopted on 16 May 1989 regarding future activities on AIDS prevention and control at Community level, medical devices used for protection against the HIV virus must afford a high level of protection; ... the design and manufacture of such products should be verified by a notified body’.

34. In other words, the legislature took the view that those devices play too delicate and important a role not to be covered by Directive 93/42 and that they constitute a kind of ‘special case’, irrespective of whether it is possible to include them in one of the other categories of product within the scope of the directive.

35. I would point out, moreover, that devices capable of preventing the transmission of diseases would in any event be covered by Directive 93/42, even if the fourth indent of Article 1(2)(a) did not exist and even if the scope of the directive were narrowly construed so as to cover exclusively devices with a ‘medical purpose’. Products for the prevention of potentially very serious diseases also fall within the category defined in the first indent, which encompasses products the purpose of which is the ‘prevention ... of disease’.

36. Furthermore, it must not be overlooked that devices for the control of conception which cannot be used to prevent the transmission of disease are often, from various points of view, significant in ‘medical’ terms. Frequently, these devices are used in consequence of a specific medical consultation and, in some cases, they can prevent – if not specifically a disease – consequences which are damaging for health (in the case, for example, mentioned by the Commission, of women for whom pregnancy would entail high risks).

37. Lastly, it should also be borne in mind that the potential consequences of defects or problems of quality in products designed to control conception are extremely significant, both from a strictly medical perspective and from a social and psychological perspective. It is perfectly understandable, therefore, that the legislature wished, always and in any event, to bring such devices within the scope of the directive.

38. It must also be added that the diagnostic and therapeutic dimension of Directive 93/42 is confirmed by the annexes thereto, in which the legislature clearly and consistently refers to use of a medical nature of the products requiring certification. In that context, one example is provided by Annex X on the clinical evaluation of the devices: the medical objective is clearly and indisputably inherent in that annex.

3. The absence of references to other objectives of Directive 93/42

39. At no point in Directive 93/42 does the legislature ever suggest the intention of protecting persons other than those whom I have just mentioned. The main purpose of the directive, as we have seen, is to protect – as persons ‘actively’ involved – those who use the products to examine and/or treat patients (doctors and nurses, and so on), and to protect – as persons ‘passively’ involved – three distinct groups of individuals: (i) the sick (patients in receipt of treatment); (ii) persons who might be sick (patients undergoing clinical investigation); and, lastly, (iii) persons who could become ill, or at least suffer serious consequences, if devices proved to be defective or unreliable (users of devices for the control of conception).

4. The role accorded to the manufacturer’s intended use of the product

40. Directive 93/42 contains various references to the manufacturer’s intended use of a product. This reveals that, far from being irrelevant, that ‘subjective’ element must in fact be taken into account in interpreting the applicable provisions.

41. I am referring here, in particular, to the introduction to the definition of ‘medical device’ set out in Article 1(2)(a). As was seen above when the text of that provision was cited, it introduces the four categories already discussed, stating that a medical device means any device ‘... *intended by the manufacturer* to be used for human beings ...’¹²

42. That reference to the manufacturer’s intention is not of itself decisive here, because the reference is to the intention that the product should be used for human beings and not that it should be used for human beings *for medical purposes*. It is important nevertheless to bear in mind that the manufacturer’s intention as regards the use of a given product is not immaterial and that categorisation under the directive cannot be based on objective factors only. If there were no reference to the manufacturer’s intention, it would be impossible clearly to delimit the category of medical devices: the medical profession uses many products which are to an extent ‘functionally’ equivalent to products used in other sectors: surgical instruments, for instance, which are often similar, in terms of how they work, to tools used by artisans to work iron or wood, but no-one would dream of calling for a hammer or a carpenter’s saw to be certified as a medical device.

5. The principle of the free movement of goods

43. Among the objectives of Directive 93/42, as set out also in the third recital in the preamble, is guaranteeing the free movement of medical devices within the territory of the European Union. More specifically, the directive seeks to reconcile the free movement of the products with the protection of patient health.

44. As the Court has pointed out, in particular with reference to the medicinal products sector, a sector regulated by rules based on similar premisses,¹³ in interpreting the requirements and limitations placed on a product a balance must be struck between the potentially conflicting principles of the protection of health, on the one hand, and free movement, on the other. From that perspective, it is therefore necessary to interpret the directive – and, consequently, the certification and CE marking requirement – by reference to a formula which respects that basic principle and confines restrictions to cases in which they appear to be justified in order to protect a higher interest.¹⁴

¹² — Emphasis added.

¹³ — Directive 2001/83/EC of the Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ 2001 L 311, p. 67). See, in particular, the fourth and fifth recitals in the preamble.

¹⁴ — See, for example, Case C-319/05 *Commission v Germany* [2007] ECR I-9811, paragraphs 62 and 71; and Case C-140/07 *Hecht-Pharma* [2009] ECR I-41, paragraph 27. See also, by analogy, Case C-6/05 *Medipac-Kazantzidis* [2007] ECR I-4557, paragraph 52.

45. In cases where a product is not used for medical purposes, but for the purposes of research on volunteers who do not have particular health problems, the need to certify that product as a medical device may legitimately be called into question.

6. Practice at European Union level and at national level

46. Nor should it be forgotten that, both at national and at European Union level, practice has apparently reflected, without exception, the approach that Directive 93/42 applies in principle only to devices intended to be used for medical purposes.

47. While that is certainly not conclusive, it would at least seem to suggest that the bodies involved in the legislative process (the Commission and the Member States) had no doubt as to how the directive should be construed.

7. The analogy with software

48. Evidence of the need to limit the application of Directive 93/42 to products intended to be used for a medical purpose can, by analogy, be found in the provision made under Article 1 of that directive in relation to software.

49. As we know, software products are used on a daily basis in medical practice and, accordingly, the legislature considered the problem of how to prevent the requirements of conformity with the directive being applied indiscriminately to any computer program that might be used in a medical setting. Here again, the solution arrived at involves focusing on the *use intended by the manufacturer* for the product. As we have seen, under Article 1 of Directive 93/42, software ‘*intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes* and necessary for [the] proper application [of the device]’, falls within the scope of the directive.¹⁵

50. That argument is not, of course, decisive and could also be used to assert the contrary: had the legislature intended to limit the scope of Directive 93/42 solely to products intended for a medical purpose, it could have done so expressly, as it did in the case of software. Here too, however, the more interesting aspect seems to me to be the reference to the manufacturer’s intention: this confirms that the objective elements which characterise a product are not the only factors which may be taken into consideration in determining whether that product is covered by the directive.

C – *The disadvantages of a literal interpretation*

51. In addition to the arguments which I have set out above, the many disadvantages – which cannot be disregarded – attaching to a broader interpretation of the scope of Directive 93/42 suggest that, at least as regards the products covered by the third indent of Article 1(2)(a), the scope of that directive should be construed as covering only those devices which are intended by the manufacturer to be used for a medical purpose.

52. First, according to the information provided in writing and at the hearing, it would no longer be possible to market products such as the ActiveTwo system, at issue in the main proceedings, if they had to be certified as medical devices under Directive 93/42.

¹⁵ — Emphasis added.

53. The ActiveTwo system is in fact flexible and modular. It is not a single item of equipment configured in a predetermined manner, but a set of different components which the purchaser buys and configures to meet his own requirements (that is to say, in practice, to suit the type of investigation to be carried out). It is precisely the intrinsically flexible nature of the ActiveTwo system that would make it impossible to make that system subject to certification as a medical device, as this requires a ‘standardised’ product the characteristics of which – such as the risk/benefit profile and its accuracy of measurement – are capable of being assessed.

54. It should further be noted that – as the Commission emphasised in its observations – Annex I to Directive 93/42, which sets out the list of essential requirements that must be met for a medical device to be accorded certification, provides under paragraph I.1 that a precondition for the certification of medical devices is that ‘any risks which may be associated with their use [should] constitute acceptable risks *when weighed against the benefits to the patient*’. It is clear that, in a case such as that before the referring court, that wording gives rise to at least two problems. On the one hand, a healthy individual who takes part voluntarily in scientific tests cannot, as has been pointed out above, be regarded as a ‘patient’: generally speaking, a patient is a person who is sick or potentially sick. On the other hand, and this is where the real problem lies, a product which is used for research, and not to diagnose or treat disease, does not, by definition, produce any *individual benefit* for the persons on whom it is used: in other words, the volunteers who take part in a scientific investigation carried out using the ActiveTwo system do not derive any direct benefit from doing so.

55. The outcome is that, so far as the individual is concerned, the risk/benefit profile of a product intended to be used purely for research purposes is, by definition, negative.¹⁶ Consequently, the application of the rules laid down in Directive 93/42 could, in principle, mean that certification for a product of that nature would always be refused.

56. However, a total ban on the marketing of a product like ActiveTwo, or any other product with similar characteristics, seems a drastic consequence of the interpretation of the directive, and one that would be hard to justify – *a fortiori* because such a ban could have an impact not only on the single market, but also on the pursuit of scientific research.

57. Secondly, if Directive 93/42 were construed as applying also to products not intended to be used for a medical purpose, where such products meet the general definition in the third indent of Article 1(2)(a), the result would be that the CE marking would have to be affixed to a great number of products in general use which, as matters stand, are very often marketed without being certified as being in conformity with the directive.

58. Such products include, first of all, products intended for ‘domestic’ use, with the same or similar functions as devices used in the medical sphere: bathroom scales, heart-rate monitors, pedometers capable of indicating calorie consumption and so on. Generally speaking, there are two main markets for products with those functions. On the one hand, there is the ‘medical-professional’ market, for which higher-performance and more expensive certified products are intended. Then there is the ‘domestic’ market, with products which are sometimes of lower quality performance, and generally (although not invariably)¹⁷ not certified as medical devices, but sold at lower prices. To require all of those products to be in conformity with Directive 93/42 would entail the compulsory ‘merger’ of the two markets and an inevitable price rise for the ‘ordinary’ consumer.

16 — At best, that profile could be neutral in the case of devices involving no risk – not even a minimal risk. On the other hand, as we know, there is no such thing as zero risk in the real world.

17 — In some cases, certain products are certified as medical devices even though they are mainly intended for non-professionals. That is a result of a commercial decision by manufacturers, linked to the product’s image and often connected to a higher product price.

59. Still more extreme would be the case of products like wigs and false nails, which, on the basis of a literal interpretation, would also be caught by the definition of medical device within the terms of the third indent, because they are in any event products which result in the ‘replacement or modification of the anatomy’. To my knowledge, no-one has ever thought of calling for products of that kind to be certified as medical devices.

60. The only way of avoiding such ‘abnormal’ categorisation is, in practice, to take into account the purpose for which a product is intended and to limit the obligation to comply with Directive 93/42 strictly to products which are intended to be used for a medical purpose.¹⁸ This actually means that only those products which are intended to be used for the purposes of diagnosis or treatment, or which are used in the context of medical procedures of any kind, are covered by the definition within the terms of the third indent.¹⁹

61. I should add that there are some health-care products in general use, such as toothbrushes, which *also* have a function in preventing illness and, if Directive 93/42 were narrowly construed, that could be taken as an indication that they should be categorised as medical devices regulated by the directive. Here again, however, no-one appears to wish for an outcome of that nature, which would be absurd.²⁰

D – Summary

62. Clearly, there are many factors to suggest that an exclusively literal interpretation of the definition of ‘medical device’ given in Directive 93/42 is not satisfactory. On the contrary, it seems more appropriate to restrict the scope of the directive and, more specifically, the scope of the third indent of Article 1(2)(a) solely to devices which are intended to be used for a medical purpose.

63. An element of clarification is needed here, however. Even if the information provided by the manufacturer is the key factor in determining whether a product is intended to be used for a medical purpose, any product which, by its very nature, is clearly intended to be used solely for a purpose of a medical nature *will have to be regarded as a medical device*, even if the manufacturer does not describe it as such. In any event, that proviso, which is designed to prevent abuse, ought not to be needed in most cases, since – including for obvious reasons of professional liability – the consistent practice of medical structures is to purchase only products which have been certified in accordance with the directive.

64. Furthermore, the fact that a product has not been categorised as a medical device should not be taken to imply that it may present a particular risk for users. All of the other general provisions to guarantee product safety continue to apply, including those which, for example, require conformity and the affixing of the CE marking to all electrical equipment,²¹ to all equipment which could cause

18 — The referring court, which is against limiting the requirement of conformity to Directive 93/42 exclusively to products intended for medical use, considers it in any event possible to rule out the application of the directive to products with regard to which the ‘investigation of a physiological process’ is not the ‘purpose’ of the actual product, but merely the ‘means’ of achieving a different purpose. In my view, that distinction does not carry conviction: the purpose of a heart-rate monitor for use in the home is to measure heart rate, just like the ECG component in the ActiveTwo system. If what the referring court is proposing is an analysis of the *further purpose* for which the product may be intended (weight loss, improving physical fitness and so on), I would point out that this brings us back to the realm of a *subjective assessment*, just like the manufacturer’s assessment of the intended use of the product. Taking that approach, if it is necessary to ascertain the ultimate purpose for which a ‘domestic’ heart-rate monitor is intended, it will also be necessary to determine the ultimate purpose for which the ActiveTwo system is intended: the conclusion is that there is no medical purpose in either case.

19 — As pointed out at the hearing also, there is no doubt that, for example, an implantable prosthesis will also constitute a medical device, as it is implanted during a surgical procedure. Whether the prosthesis is implanted for therapeutic or for purely aesthetic reasons is therefore irrelevant.

20 — See also the Commission’s guidelines, MEDDEV 2.1/1, cited in footnote 9, paragraph I.1(d).

21 — Directive 2006/95/EC of the European Parliament and of the Council of 12 December 2006 on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits (codified version) (OJ 2006 L 374, p. 10).

problems relating to electromagnetic compatibility²² and so on. Paradoxically, as the Commission emphasised at the hearing, in many cases, other forms of certification lay down requirements which are even more stringent than those imposed in relation to medical devices. While a medical device may, generally, entail risks, including significant risks, provided that those risks are offset by adequate benefits, the other forms of certification do not, in the majority of cases, permit a similar balance to be struck and tend simply to require that any possible risk be minimised.

V – Conclusion

65. In the light of the foregoing considerations, I propose that the Court reply as follows to the question referred for a preliminary ruling by the Bundesgerichtshof:

A product which is intended by the manufacturer to be applied for human beings for the purpose of investigation of a physiological process constitutes a medical device, within the terms of the third indent of Article 1(2)(a) of Directive 93/42/EEC, only where it is intended for a medical purpose.

²² — Directive 2004/108/EC of the European Parliament and of the Council of 15 December 2004 on the approximation of the laws of the Member States relating to electromagnetic compatibility and repealing Directive 89/336/EEC (OJ 2004 L 390, p. 24).