JUDGMENT OF THE COURT (Fifth Chamber)
20 March 1997 *

In Case C-294/96,

Commission of the European Communities, represented by Hendrik van Lier, Legal Adviser, and Jean-François Pasquier, a national civil servant on secondment to its Legal Service, acting as Agents, with an address for service in Luxembourg at the office of Carlos Gómez de la Cruz, of its Legal Service, Wagner Centre, Kirchberg,

applicant,

v

Kingdom of Belgium, represented by Jan Devadder, General Adviser at the Ministry of Foreign Affairs, External Trade and Cooperation with Developing Countries, acting as Agent, with an address for service in Luxembourg at the Belgian Embassy, 4, Rue des Girondins,

defendant,

APPLICATION for a declaration that, by failing to adopt, within the prescribed time-limit, the laws, regulations and administrative provisions necessary to comply with Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ 1993 L 169, p. 1), the Kingdom of Belgium has failed to fulfil its obligations under the EC Treaty,

* Language of the case: French.

THE COURT (Fifth Chamber),

composed of: J. C. Moitinho de Almeida, President of the Chamber (Judge-Rapporteur), L. Sevón, D. A. O. Edward, J.-P. Puissochet and P. Jann, Judges,

Advocate General: C. O. Lenz,
Registrar: R. Grass,

having regard to the Report of the Judge-Rapporteur,

after hearing the Opinion of the Advocate General at the sitting on 18 February 1997,

gives the following

Judgment

1 By application lodged at the Court Registry on 9 September 1996, the Commission of the European Communities brought an action under Article 169 of the EC Treaty for a declaration that, by failing to adopt, within the prescribed time-limit, the laws, regulations and administrative provisions necessary to comply with Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ 1993 L 169, p. 1, 'the directive'), the Kingdom of Belgium has failed to fulfil its obligations under the EC Treaty.

2 Article 22 of the directive states that the Member States are to adopt and publish the laws, regulations and administrative provisions necessary to comply with the Directive by 1 July 1994 and that they are to inform the Commission thereof immediately.

3 Since it had not been notified of the provisions adopted by the Kingdom of Belgium in order to comply with the directive, the Commission gave the Belgian Government formal notice by letter of 20 January 1995 to submit its observations within two months.

4 Receiving no reply, the Commission sent a reasoned opinion to the Kingdom of Belgium on 26 January 1996 calling upon it to adopt the measures required to comply with that opinion within two months.

5 Since it was not notified of any measures transposing the directive into national law, the Commission brought the present action.

6 The Kingdom of Belgium does not dispute that the directive has not been transposed into national law within the prescribed time-limit. It merely states that the draft royal decree designed to implement the directive is in the process of being finalized by a working party.

7 Since the directive has not been transposed into national law within the prescribed time-limit, the action brought by the Commission in that regard must be considered to be well founded.

8 It must therefore be held that, by failing to adopt, within the prescribed time-limit, the laws, regulations and administrative provisions necessary to comply with the directive, the Kingdom of Belgium has failed to fulfil its obligations under Article 22 thereof.

Costs

9 Under Article 69(2) of the Rules of Procedure, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings. As the Commission has applied for costs, and the Kingdom of Belgium has been unsuccessful in its defence, it must be ordered to pay the costs.

On those grounds,

THE COURT (Fifth Chamber)

hereby:

1. Declares that, by failing to adopt, within the prescribed time-limit, the laws, regulations and administrative provisions necessary to comply with Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, the Kingdom of Belgium has failed to fulfil its obligations under Article 22 thereof;

2. Orders the Kingdom of Belgium to pay the costs.

Moitinho de Almeida Sevón Edward

Puissochet Jann

Delivered in open court in Luxembourg on 20 March 1997.

R. Grass J. C. Moitinho de Almeida

Registrar President of the Fifth Chamber