

Council Directive of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (90/385/EEC)

COUNCIL DIRECTIVE

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on the approximation of the laws of the Member States relating to active implantable medical devices

(90/385/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100a thereof,

Having regard to the proposal from the Commission⁽¹⁾,

In cooperation with the European Parliament⁽²⁾,

Having regard to the opinion of the Economic and Social Committee⁽³⁾,

Whereas in each Member State active implantable medical devices must give patients, users and other persons a high level of protection and achieve the intended level of performance when implanted in human beings;

Whereas several Member States have sought to ensure that level of safety by mandatory specifications relating both to the technical safety features and the inspection procedures for such devices; whereas those specifications differ from one Member State to another;

Whereas national provisions ensuring that safety level should be harmonized in order to guarantee the free movement of active implantable medical devices without lowering existing and justified levels of safety in the Member States;

Whereas harmonized measures must be distinguished from measures taken by Member States to manage the financing of public health and sickness insurance schemes directly or indirectly concerning such devices; whereas, therefore, such provisions do not affect the right of Member States to implement the abovementioned measures in compliance with Community law;

Whereas maintaining or improving the level of protection achieved in Member States constitutes one of this Directive's essential objectives as defined by the essential requirements;

Whereas rules governing active implantable medical devices can be confined to those provisions needed to satisfy the essential requirements; whereas, because they are essential, these requirements must replace corresponding national provisions;

Whereas, in order to facilitate proof of conformity with these essential requirements and to permit monitoring of that conformity, it is desirable to have Europe-wide harmonized standards in respect of the prevention of risks in connection with the design, manufacture and packaging of

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active implantable medical devices; whereas such standards harmonized at European level are drawn up by private-law bodies and must retain their status as non-mandatory texts; whereas, to that end, the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (Cenelec) are recognized as being the competent bodies to adopt harmonized standards in accordance with the general guidelines for cooperation between the Commission and these two bodies, signed on 13 November 1984; whereas, for the purposes of this Directive, a harmonized standard is a technical specification (European standard or harmonization document) adopted by either or both of these bodies, as instructed by the Commission pursuant to the provisions of Council Directive 83/189/EEC of 28 March 1983 laying down a procedure for the provision of information in the field of technical standards and regulations⁽⁴⁾, as last amended by Directive 88/182/EEC⁽⁵⁾, and under the abovementioned general guidelines;

Whereas evaluation procedures have to be established and accepted by common accord between the Member States in accordance with Community criteria;

Whereas the specific nature of the medical sector makes it advisable to make provision for the notified body and the manufacturer or his agent established in the Community to fix, by common accord, the time limits for completion of the evaluation and verification operations for the conformity of devices,

HAS ADOPTED THIS DIRECTIVE:

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- (1) OJ No C 14, 18.1.1989, p. 4.
- (2) OJ No C 120, 16.5.1989, p. 75, and
OJ No C 149, 18.6.1990.
- (3) OJ No C 159, 26.6.1989, p. 47.
- (4) OJ No L 109, 26.4.1983, p. 8.
- (5) OJ No L 81, 26.3.1988, p. 75.