

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)

*Article 12*

1 Devices other than those which are custom made or intended for clinical investigations considered to meet the essential requirements referred to in Article 3 must bear the [F1CE marking of conformity.

2 The CE marking] of conformity, as shown in Annex 9, must appear in a visible, legible and indelible form on the sterile pack and, where appropriate, on the sales packaging, if any, and on the instruction leaflet.

[F1It must be followed by the identification number of the notified body responsible for implementation of the procedures set out in Annexes 2, 4 and 5.]

[F13 The affixing of markings on the devices which are likely to deceive third parties as to the meaning and form of the CE marking shall be prohibited. Any other marking may be affixed to the packaging or to the instruction leaflet accompanying the device provided that the visibility and legibility of the CE marking is not hereby reduced.]

**Textual Amendments**

**F1** Substituted by Council Directive 93/68/EEC of 22 July 1993 amending Directives 87/404/EEC (simple pressure vessels), 88/378/EEC (safety of toys), 89/106/EEC (construction products), 89/336/EEC (electromagnetic compatibility), 89/392/EEC (machinery), 89/686/EEC (personal protective equipment), 90/384/EEC (non-automatic weighing instruments), 90/385/EEC (active implantable medicinal devices), 90/396/EEC (appliances burning gaseous fuels), 91/263/EEC (telecommunications terminal equipment), 92/42/EEC (new hot-water boilers fired with liquid or gaseous fuels) and 73/23/EEC (electrical equipment designed for use within certain voltage limits).