

Table of Contents

ACTIVE IMPLANTABLE MEDICAL DEVICE DIRECTIVE (AIMDD)

including amendments and corrections, the latest being Directive 2007/47/EC,
published as a consolidated text at

<http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:01990L0385-20071011&qid=1470302197220&from=EN>

*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)*

PREFACE	"THE COUNCIL OF THE EUROPEAN COMMUNITIES,... ...HAS ADOPTED THIS DIRECTIVE:"	2
	<i>(Note: The articles of the AIMDD do not contain titles. These titles are copied from the MDD.)</i>	
Article 1	Definitions, scope	3
Article 2	Placing on the market and putting into service	5
Article 3	Essential requirements	5
Article 4	Free movement	6
Article 5	Reference to standards	6
Article 6	Committee on Standards and Technical Regulations	7
Article 7	Safeguard clause	7
Article 8	Information on incidents occurring following placing of devices on the market	8
Article 9	Conformity assessment procedures	8
Article 9a		9
Article 10	Clinical investigation	10
Article 10a	Registration of persons responsible for placing devices on the market	10
Article 10b	European databank	11
Article 10c	Particular health monitoring measures	11
Article 11	Notified bodies	12
Article 12	CE marking	13
Article 13	Wrongly affixed CE marking	13
Article 14	Decision in respect of refusal or restriction	13
Article 15	Confidentiality	14
Article 15a	Cooperation	14
Article 16	Implementation, transitional provisions	14
Article 17	"This Directive is addressed to the Member States."	14

ANNEX 1	ESSENTIAL REQUIREMENTS	15
I.	GENERAL REQUIREMENTS	15
II.	REQUIREMENTS REGARDING DESIGN AND CONSTRUCTION	15
ANNEX 2	EC DECLARATION OF CONFORMITY (Complete quality assurance system)	19
1. to 2.	(no title)	19
3.	Quality system	19
4.	Examination of the design of the product	21
5.	Surveillance	21
6.	Administrative provisions	22
7.	Application to the devices referred to in Article 1(4a)	22
ANNEX 3	EC TYPE-EXAMINATION	23
1. to 3.	(no title)	23
4.	“The notified body shall:”	23
5. to 6.	(no title)	24
7.	Administrative provisions	24
ANNEX 4	EC VERIFICATION	25
1. to 4.	(no title)	25
5.	“The notified body shall...”	25
6.	Statistical verification	25
7.	Application to the devices referred to in Article 1(4a)	26
ANNEX 5	EC DECLARATION OF CONFORMITY TO TYPE (Assurance of production quality)	27
1. to 2.	(no title)	27
3.	Quality system	27
4.	Surveillance	28
5.	“The notified body shall...”	28
6.	Application to the devices referred to Article 1(4a)	29
ANNEX 6	STATEMENT CONCERNING DEVICES INTENDED FOR SPECIAL PURPOSES	30
ANNEX 7	CLINICAL EVALUATION	32
1.	General provisions	32
2.	Clinical investigation	32
2.1.	<i>Purpose</i>	32
2.2.	<i>Ethical consideration</i>	32
2.3.	<i>Methods</i>	33
ANNEX 8	MINIMUM CRITERIA TO BE MET WHEN DESIGNATING INSPECTION BODIES TO BE NOTIFIED	34
ANNEX 9	CE CONFORMITY MARKING	35