

ISO 14708-4:2008-11 (E)

Implants for surgery - Active implantable medical devices - Part 4: Implantable infusion pumps

Contents		Page
Foreword		v
Introduction		vi
1	Scope	1
2	Normative references	1
3	Terms and definitions	2
4	Symbols and abbreviated terms	3
5	General requirements for non-implantable parts	3
6	Requirements for particular active implantable medical devices	3
7	General arrangement of the packaging	5
8	General markings for active implantable medical devices	5
9	Markings on the sales packaging	6
10	Construction of the sales packaging	6
11	Markings on the sterile pack	6
12	Construction of the non-reusable pack	7
13	Markings on the active implantable medical device	7
14	Protection from unintentional biological effects caused by the active implantable medical device	7
15	Protection from harm to the patient or user caused by external physical features of the active implantable medical device	8
16	Protection from harm to the patient caused by electricity	8
17	Protection from harm to the patient caused by heat	9
18	Protection from ionizing radiation released or emitted from the active implantable medical device	9
19	Protection from unintended effects caused by the device	9
20	Protection of the device from damage caused by external defibrillators	10
21	Protection of the device from changes caused by high-power electrical fields applied directly to the patient	10
22	Protection of the active implantable medical device from changes caused by miscellaneous medical treatments	10
23	Protection of the active implantable medical device from mechanical forces	10
24	Protection of the active implantable medical device from damage caused by electrostatic discharge	11
25	Protection of the active implantable medical device from damage caused by atmospheric pressure changes	11
26	Protection of the active implantable medical device from damage caused by temperature changes	11
27	Protection of the active implantable medical device from electromagnetic non-ionizing radiation	11
28	Accompanying documentation	17

Annex AA (informative) Relationship between the fundamental principles in ISO/TR 14283 [8] and the clauses of this part of ISO 14708	20
Annex BB (informative) Relationship between the clauses of this part of ISO 14708 and the fundamental principles listed in Annex AA	30
Annex CC (informative) Rationale	32
Bibliography	41