

## Contents

Foreword .....	5
Introduction.....	6
1 Scope.....	7
2 Normative references.....	7
3 Terms and definitions .....	7
4 Symbols (and abbreviated terms).....	8
5 General requirements for ACTIVE IMPLANTABLE MEDICAL DEVICES .....	8
6 Requirements for particular ACTIVE IMPLANTABLE MEDICAL DEVICES .....	8
7 General arrangement of the packaging.....	8
8 General markings for ACTIVE IMPLANTABLE MEDICAL DEVICES.....	9
9 Markings on the sales packaging.....	9
10 Construction of the sales packaging .....	9
11 Markings on the sterile pack.....	9
12 Construction of the non-reusable pack .....	9
13 Markings on the ACTIVE IMPLANTABLE MEDICAL DEVICE .....	9
14 Protection from unintentional biological effects being caused by the ACTIVE IMPLANTABLE MEDICAL DEVICE.....	9
15 Protection from harm to the patient or user caused by external physical features of the ACTIVE IMPLANTABLE MEDICAL DEVICE .....	9
16 Protection from harm to the patient caused by electricity .....	9
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 .....	10
19 Protection from unintended effects caused by the ACTIVE IMPLANTABLE MEDICAL DEVICE .....	10
20 Protection of the ACTIVE IMPLANTABLE MEDICAL DEVICE from damage caused by external defibrillators .....	11
21 Protection of the ACTIVE IMPLANTABLE MEDICAL DEVICE from changes caused by electrical fields applied directly to the patient .....	11

<b>22 Protection of the ACTIVE IMPLANTABLE MEDICAL DEVICE from changes caused by miscellaneous medical treatments.....</b>	<b>11</b>
<b>23 Protection of the ACTIVE IMPLANTABLE MEDICAL DEVICE from mechanical forces .....</b>	<b>12</b>
<b>24 Protection of the ACTIVE IMPLANTABLE MEDICAL DEVICE from damage caused by electrostatic discharge.....</b>	<b>13</b>
<b>25 Protection of the ACTIVE IMPLANTABLE MEDICAL DEVICE from damage caused by atmospheric pressure changes .....</b>	<b>13</b>
<b>26 Protection of the ACTIVE IMPLANTABLE MEDICAL DEVICE from damage caused by temperature changes.....</b>	<b>13</b>
<b>27 Protection of the active implantable medical device from electromagnetic non-ionizing radiation .....</b>	<b>13</b>
<b>28 Accompanying documentation .....</b>	<b>24</b>
<b>Annex AA (normative) Relationship between the fundamental principles in ISO/TR 14283 and the clauses of this part of ISO 14708.....</b>	<b>26</b>
<b>Annex BB (informative) Rationale .....</b>	<b>35</b>
<b>Annex CC (informative) Guidance — Test plan.....</b>	<b>45</b>
<b>Bibliography .....</b>	<b>46</b>