

# ISO/TR 14283:2018-01 (E)

## Implants for surgery - Essential principles of safety and performance

---

<b>Contents</b>		<b>Page</b>
Foreword .....		iv
Introduction .....		v
<b>1</b>	<b>Scope .....</b>	<b>1</b>
<b>2</b>	<b>Normative references .....</b>	<b>1</b>
<b>3</b>	<b>Terms and definitions .....</b>	<b>1</b>
<b>4</b>	<b>Application of essential principles .....</b>	<b>4</b>
<b>5</b>	<b>Essential principles applicable to implants .....</b>	<b>4</b>
5.1	General .....	4
5.2	Chemical, physical and biological properties .....	5
5.3	Infection and microbial contamination .....	5
5.4	Implants incorporating a substance considered to be a medicinal product/drug .....	6
5.5	Implants incorporating materials of biological origin .....	6
5.6	Environmental properties .....	7
5.7	Implants with a diagnostic or measuring function .....	8
5.8	Protection against radiation .....	8
5.8.1	General .....	8
5.8.2	Intended radiation .....	8
5.8.3	Unintended radiation .....	9
5.8.4	Ionizing radiation .....	9
5.9	Implants that incorporate software .....	9
5.10	Active implants and devices connected to them .....	9
5.11	Protection against mechanical risks .....	10
5.12	Protection against the risks posed to the patient or user by supplied energy or substances .....	10
5.13	Label and Instructions for Use .....	11
5.13.1	General principles .....	11
5.13.2	Content of the label .....	12
5.13.3	Content of the instructions for use .....	13
5.14	Clinical evaluation .....	15
Annex A (informative)	Corresponding regulatory requirements .....	16
Bibliography .....		19