

ISO/TR 14283:2018-01 (E)

Implants for surgery - Essential principles of safety and performance

Contents		Page
Foreword		iv
Introduction		v
1	Scope	1
2	Normative references	1
3	Terms and definitions	1
4	Application of essential principles	4
5	Essential principles applicable to implants	4
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