ISO/TR 14283:2004-07 (E)

Implants for surgery - Fundamental principles

Contents

Page

Foreword iv

Introduction v

1 Scope 1

2 Terms and definitions 1

3 General principles 2

4 Specific principles regarding design and construction 3
4.1 Chemical, physical and biological properties 3
4.2 Infection and microbial contamination 4
4.3 Construction and environmental properties 4
4.4 Implants with a measuring function 5
4.5 Protection against radiation 5
4.5.1 General 5
4.5.2 Intended radiation 5
4.5.3 Unintended radiation 5
4.5.4 Instructions 5
4.6 Ionizing radiation 6
4.7 Principles for implants connected to or equipped with an energy source 6
4.7.1 General 6
4.7.2 Protection against electrical risks 6
4.7.3 Protection against mechanical risks 6
4.7.4 Protection against the risks posed to the patient by energy supplies or substances 7
4.8 Information supplied by the manufacturer 7
4.9 Clinical evaluation 9

Annex A (informative) Correspondence to some regulatory documents 10

A.1 General 10
A.2 European Economic Area 10
A.3 Australia 10
A.4 Canada 10
A.5 China 11
A.6 Japan 11

Bibliography 15