

### Contents

	Foreword
	Introduction
1	Scope
2	Normative references
3	Terms and definitions
4	Categorization of medical devices
4.1	Categorization by nature of contact
4.1.1	General
4.1.2	Non-contact devices
4.1.3	Surface-contacting devices
4.1.4	External communicating devices
4.1.5	Implant devices used in dentistry
4.2	Categorization by duration of contact
4.2.1	General
4.2.2	Limited exposure devices
4.2.3	Prolonged exposure devices
4.2.4	Permanent contact devices
5	Biological evaluation process
5.1	General
5.2	Selection of tests and overall assessment
5.3	Selection of test methods
5.4	Types of test
5.4.1	General
5.4.2	Physical and chemical characterization
5.4.3	Group I
5.4.4	Group II
5.4.5	Group III
5.5	Re-evaluation of biocompatibility
6	Test procedures specific to dental materials
6.1	Recommendations for sample preparation
6.1.1	General
6.1.2	General recommendations for sample preparation
6.1.3	Specific recommendations for light curing materials
6.1.4	Specific recommendations for chemically setting materials
6.1.5	Positive control material
6.2	Agar diffusion test
6.2.1	Objective
6.2.2	Cell line
6.2.3	Culture medium, reagents and equipment
6.2.4	Sample preparation
6.2.5	Controls
6.2.6	Test procedure
6.2.7	Parameters of assessment
6.2.8	Assessment of results
6.2.9	Test report
6.3	Filter diffusion test
6.3.1	Objective
6.3.2	Cell line

- 6.3.3 Culture medium, reagents and equipment
- 6.3.4 Sample preparation
- 6.3.5 Controls
- 6.3.6 Test procedure
- 6.3.7 Assessment of cell damage
- 6.3.8 Assessment of results
- 6.3.9 Test report
- 6.4 Pulp and dentine usage test
- 6.4.1 Objective
- 6.4.2 Animals and animal welfare
- 6.4.3 Test procedure
- 6.4.3.1 Preparation of animals
- 6.4.3.2 Treatment of teeth
- 6.4.3.3 Euthanasia
- 6.4.3.4 Preparation of slides
- 6.4.3.5 Preservation of the dental pulp
- 6.4.3.6 Assessment of dentine and dental pulp
- 6.4.3.7 Odontoblast cell survival analysis (optional)
- 6.4.4 Assessment of results
- 6.4.4.1 General
- 6.4.4.2 Statistical analysis of remaining dentine thickness
- 6.4.5 Test report
- 6.5 Pulp capping test
- 6.5.1 Objective
- 6.5.2 Animals and animal welfare
- 6.5.3 Test procedure
- 6.5.3.1 Preparation of animals
- 6.5.3.2 Treatment of teeth
- 6.5.3.3 Preparation of slides
- 6.5.3.4 Assessment of dental pulp
- 6.5.4 Assessment of results
- 6.5.5 Test report
- 6.6 Endodontic usage test
- 6.6.1 Objective
- 6.6.2 Animals and animal welfare
- 6.6.3 Test procedure
- 6.6.3.1 Preparation of animals
- 6.6.3.2 Treatment of teeth
- 6.6.3.3 Preparation of slides
- 6.6.3.4 Assessment of tissues
- 6.6.4 Assessment of results
- 6.6.5 Test report

**Annex A (informative) Types of test to be considered for evaluation of biocompatibility of medical devices used in dentistry**

**Annex B (informative) Dentine barrier cytotoxicity test**

- B.1 Objective
- B.2 Apparatus and materials
- B.2.1 Cells
- B.2.2 Culture medium
- B.2.3 Reagents
- B.2.4 Equipment
- B.3 Test procedure
- B.3.1 Cell culture preparation
- B.3.1.1 Three-dimensional cell cultures
- B.3.1.2 Monolayer cultures
- B.3.2 Preparation of dentine slices
- B.3.2.1 Human origin
- B.3.2.2 Bovine origin
- B.3.2.3 Treatment of dentine slices
- B.3.2.4 Perfusion assembly
- B.3.2.4.1 Minucells device
- B.3.2.4.2 Assembly of the ADA-perfusion chamber

- B.4** Control material
- B.5** Assessment of results
- B.6** Test report

**Annex C (informative) Endosseous dental implant usage test**

- C.1** General
- C.2** Test method
  - C.2.1** Test protocol
  - C.2.2** Animals and animal welfare
    - C.2.2.1** Animal welfare
    - C.2.2.2** Test animals
    - C.2.2.3** Number of animals
  - C.2.3** Test procedure
    - C.2.3.1** Test specimens
    - C.2.3.2** Control specimens
    - C.2.3.3** Surgical preparation of sites for the placement of the dental implant and control
    - C.2.3.4** Placement of dental implant systems
    - C.2.3.5** Test periods
    - C.2.3.6** Dental plaque control
    - C.2.3.7** Clinical and radiographic examination
    - C.2.3.8** Termination of the test period
  - C.2.4** Evaluation
    - C.2.4.1** Clinical evaluation
    - C.2.4.2** Radiographic assessment
    - C.2.4.3** Specimen retrieval
    - C.2.4.4** Specimen preparation for histopathological examination
    - C.2.4.5** Microscopic assessment
    - C.2.4.6** Statistical analysis
  - C.2.5** Test report

Page count: 43