

ISO 7405:2008-12 (E)

Dentistry - Evaluation of biocompatibility of medical devices used in dentistry

Contents		Page
Foreword		iv
Introduction		v
1	Scope	1
2	Normative references	1
3	Terms and definitions	2
4	Categorization of medical devices	3
4.1	Categorization by nature of contact	3
4.2	Categorization by duration of contact	3
5	Biological evaluation process	4
5.1	General	4
5.2	Selection of tests and overall assessment	4
5.3	Selection of test methods	4
5.4	Types of test	5
5.5	Re-evaluation of biocompatibility	6
6	Test procedures specific to dental materials	6
6.1	Recommendations for sample preparation	6
6.2	Agar diffusion test	8
6.3	Filter diffusion test	10
6.4	Pulp and dentine usage test	13
6.5	Pulp capping test	17
6.6	Endodontic usage test	19
Annex A (informative) Types of test to be considered for evaluation of biocompatibility of medical devices used in dentistry		23
Annex B (informative) Dentine barrier cytotoxicity test		25
Annex C (informative) Acute toxicity testing		32
Bibliography		33