

DIN EN 1641:2010-02 (E)

Dentistry - Medical devices for dentistry - Materials

Contents		Page
age Foreword		3
Introduction		4
1	Scope	5
2	Normative references	5
3	Terms and definitions	6
4	Requirements	7
4.1	General	7
4.2	Chemical and physical properties	7
4.2.1	Composition	7
4.2.2	Biocompatibility	7
4.2.3	Material properties	7
4.3	Control of contamination	7
4.4	Restorative materials used in combination	7
4.5	Clinical evaluation	8
4.6	Marking, labelling and information supplied by the manufacturer	8
4.6.1	General	8
4.6.2	Symbols	8
4.6.3	Label	8
4.6.4	Instructions for use	8
Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC		10
Bibliography		11