

DIN EN 1639:2010-02 (E)

Dentistry - Medical devices for dentistry - Instruments

Contents		Page
Foreword		3
Introduction		4
1 Scope		5
2 Normative references		5
3 Terms and definitions		7
4 Requirements		8
4.1 General		8
4.2 Chemical and physical properties		8
4.2.1 General		8
4.2.2 Contaminants and residues		8
4.2.3 Contact with substances		9
4.3 Control of contamination		9
4.3.1 General		9
4.3.2 Instruments supplied sterile		9
4.3.3 Instruments supplied non-sterile		9
4.4 Construction and environmental properties		9
4.5 Instruments connected to or equipped with an energy source		10
4.6 Protection against electrical risks		10
4.7 Protection against mechanical and thermal risks		10
4.7.1 Vibration		10
4.7.2 Noise		10
4.7.3 Electricity, gas or hydraulic and pneumatic energy		10
4.7.4 Surface temperature		10
4.8 Controls and indicators		11
4.9 Clinical evaluation		11
4.10 Marking, labelling and information supplied by the manufacturer		11
4.10.1 General		11
4.10.2 Symbols		11
4.10.3 Marking		11
4.10.4 Label		12
4.10.5 Detachable components		12
4.10.6 Instructions for use		12
of EU Directive 93/42/EEC		14
Bibliography		15