

DIN EN ISO 13504:2012-10 (E)

Dentistry - General requirements for instruments and related accessories used in dental implant placement and treatment (ISO 13504:2012)

Contents		Page
Foreword		3
Introduction		4
1	Scope	5
2	Normative references	5
3	Terms and definitions	6
3.2	Instruments	6
3.3	Stainless steel	6
4	Classification	7
4.1	Intended usage (application)	7
4.2	Tissue contact	7
4.3	Reprocessing	7
5	Intended performance	7
6	Performance attributes	7
7	Material selection	8
8	Performance evaluation	8
8.1	General	8
8.2	Pre-clinical evaluation	8
8.3	Clinical evaluation	8
9	Manufacturing	9
9.1	General	9
9.2	Technical documentation	9
10	Reprocessing	9
10.1	Products supplied sterile	9
10.2	Products provided non-sterile	9
10.3	Reprocessing information	9
11	Information to be supplied by the manufacturer	9
11.1	General	9
11.2	Marking on instruments	9
11.3	Labelling on the package	10
11.4	Instructions for use	10
Annex A (normative) Materials found acceptable for instrument manufacture		11
Annex B (informative) Cross-referencing of steel grades specified in international, regional or national standards		17
Bibliography		19