

DIN EN ISO 21534:2007-12 (E)

Non-active surgical implants - Joint replacement implants - Particular requirements (ISO 21534:2007)

Contents		Page
Foreword		4
Introduction		5
1	Scope	6
2	Normative references	6
3	Terms and definitions	7
4	Intended performance	7
5	Design attributes	8
5.1	General	8
5.2	Surface finish of metallic or ceramic implants articulating on ultra-high-molecular-weight polyethylene (UHMWPE)	8
5.3	Surface finish of metallic or ceramic partial implants	8
5.4	Surfaces of convex, spherically-conforming metallic or ceramic implants articulating on UHMWPE	8
5.5	Surfaces of spherically-conforming metallic or ceramic partial implants	8
5.6	Surfaces of concave, spherically-conforming UHMWPE components	8
6	Materials	9
6.1	General	9
6.2	Dissimilar metals or alloys	9
7	Design evaluation	9
7.1	General	9
7.2	Preclinical evaluation	9
7.3	Clinical investigation	10
7.4	Post market surveillance	10
8	Manufacture and inspection	10
8.1	General	10
8.2	Metal surfaces	10
8.3	Plastic surfaces	10
8.4	Ceramic surfaces	10
9	Sterilization	11
9.1	General	11
9.2	Expiry	11
10	Packaging	11
11	Information supplied by the manufacturer	11
11.1	General	11
11.2	Labelling of implants for use on one side of the body only	11
11.3	Instructions for orientation of implants	11
11.4	Markings for orientation of the implants	11
11.5	Placing of markings on implants	11
11.6	Restrictions on use	12

11.7	Re-sterilization of zirconia ceramics	12
11.8	Labelling of implants for use with or without bone cement	12
Annex A (informative) List of International Standards for materials found acceptable for the manufacture of implants		13
Annex B (informative) List of International Standards for materials found acceptable or not acceptable for articulating surfaces of implants		14
Annex C (informative) List of materials found acceptable or non-acceptable for metallic combinations for non-articulating contacting surfaces of implants		16
Bibliography		17
Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC		19