

ISO 21535:2007-10 (E)

Non-active surgical implants - Joint replacement implants - Specific requirements for hip-joint replacement implants

Contents		Page
Foreword		iv
Introduction		v
1	Scope	1
2	Normative references	1
3	Terms and definitions	1
4	Intended performance	2
5	Design attributes	3
5.1	General	3
5.2	Tolerances and dimensions	3
5.3	Thickness of UHMWPE in acetabular components and bipolar heads	3
6	Materials	3
7	Design evaluation	4
7.1	General	4
7.2	Preclinical evaluation	4
8	Manufacture	4
9	Sterilization	5
10	Packaging	5
11	Information to be supplied by the manufacturer	5
11.1	General	5
11.2	Dimensions	5
11.3	Structural and functional compatibility of components	5
11.4	Marking	5
11.5	Information for the patient	6
Annex A (informative) Evaluation of relative angular motion of components		7
Bibliography		9