

DIN EN ISO 21535:2017-04 (E)

Non-active surgical implants - Joint replacement implants - Specific requirements for hip-joint replacement implants (ISO 21535:2007 + Amd 1:2016) (includes Amendment :2016)

Contents

Page

Foreword to DIN EN ISO 21535:2017	3
A₁ European foreword to Amendment A1 of DIN EN ISO 21535 A₁	4
Introduction	5
1 Scope	6
2 Normative references	6
3 Terms and definitions	6
4 Intended performance	7
5 Design attributes	8
5.1 General.....	8
5.2 Tolerances and dimensions.....	8
5.2.1 Tolerances and dimensions of taper connections.....	8
5.2.2 Tolerances on diameters of articulating surfaces.....	8
5.2.3 A₁ Sphericity of femoral heads and plastic acetabular components	8
5.2.4 Surface finish of femoral heads and plastic acetabular components.....	8
5.3 Thickness of UHMWPE in acetabular components and bipolar heads	8
5.3.1 Acetabular components	8
5.3.2 Bipolar heads.....	8
6 Materials.....	9
7 Design evaluation.....	9
7.1 General.....	9
7.2 Preclinical evaluation.....	9
7.2.1 Endurance testing of femoral components	9
7.2.2 Endurance properties of A₁ deleted A₁ neck region of stemmed femoral components	9
7.2.3 Pull-off characteristics of A₁ femoral A₁ heads.....	9
7.2.4 Wear testing of total hip joint replacements.....	9
7.2.5 Minimum and maximum angles.....	9
8 Manufacture	10
9 Sterilization	10
10 Packaging	10
11 Information to be supplied by the manufacturer	10
11.1 General.....	10
11.2 Dimensions.....	10
11.3 Structural and functional compatibility of components	10
11.4 Marking.....	11
11.5 Information for the patient	11

Annex A (informative) Evaluation of relative angular motion of components.....	12
Bibliography.....	14
Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC	15
Annex ZB (informative) ^[A1] Correlations between undated normative references and dated EN and ISO standards ^[A1].....	17