

DIN EN ISO 21536:2024-10 (E)

Non-active surgical implants - Joint replacement implants - Specific requirements for knee-joint replacement implants (ISO 21536:2023)

Contents	Page
European foreword	3
Annex ZA (informative) Relationship between this European standard and the General Safety and Performance Requirements of Regulation (EU) 2017/745 aimed to be covered	4
Foreword	8
Introduction	10
1 Scope	11
2 Normative references	11
3 Terms and definitions	12
4 Intended performance	16
5 Design attributes	16
5.1 General.....	16
5.2 Tolerances and dimensions.....	17
5.2.1 Tolerances and dimensions of taper connections.....	17
5.2.2 Surface finish of non-articulating regions of knee joint components.....	18
5.2.3 Surface finish of articulating surfaces of knee joint components.....	18
5.3 Thickness of knee joint components.....	18
5.3.1 General.....	18
5.3.2 Thickness of UHMWPE in tibial inserts, monobloc tibial components, mobile-bearing components, patella inserts and monobloc patellar components.....	18
5.3.3 Thickness of metal and ceramic in femoral components, tibial trays and patellar trays.....	19
6 Materials	20
7 Design evaluation	20
7.1 General.....	20
7.2 Pre-clinical evaluation.....	20
7.2.1 General.....	20
7.2.2 Test methods and performance requirements.....	22
7.3 Clinical investigation.....	28
7.4 Post market surveillance.....	29
8 Manufacture	29
9 Sterilization	29
10 Packaging	29
11 Information to be supplied by the manufacturer	29
11.1 General.....	29
11.2 Product type and dimensions.....	29
11.3 Constructional and functional compatibility of components.....	30
11.4 Marking.....	30
11.5 Information for the patient.....	30
11.6 Electronic instructions for use.....	30
Annex A (informative) Evaluation of the range of relative angular motion of components of fully constrained total knee joint replacement implants	31
Bibliography	32