

# DIN EN ISO 21536:2007-12 (E)

## Non-active surgical implants - Joint replacement implants - Specific requirements for knee-joint replacement implants (ISO 21536:2007)

---

<b>Contents</b>	<b>Page</b>
<b>Foreword</b> .....	<b>3</b>
<b>Introduction</b> .....	<b>4</b>
<b>1 Scope</b> .....	<b>5</b>
<b>2 Normative references</b> .....	<b>5</b>
<b>3 Terms and definitions</b> .....	<b>5</b>
<b>4 Intended performance</b> .....	<b>6</b>
<b>5 Design attributes</b> .....	<b>6</b>
<b>5.1 General</b> .....	<b>6</b>
<b>5.2 Thickness of ultra-high molecular weight polyethylene (UHMWPE) in tibial components and meniscal components</b> .....	<b>6</b>
<b>5.3 Finish of non-articulating regions of metallic knee joint components</b> .....	<b>7</b>
<b>6 Materials</b> .....	<b>7</b>
<b>7 Design evaluation</b> .....	<b>7</b>
<b>7.1 General</b> .....	<b>7</b>
<b>7.2 Preclinical evaluation</b> .....	<b>7</b>
<b>8 Manufacture</b> .....	<b>7</b>
<b>9 Sterilization</b> .....	<b>8</b>
<b>10 Packaging</b> .....	<b>8</b>
<b>11 Information to be supplied by the manufacturer</b> .....	<b>8</b>
<b>11.1 General</b> .....	<b>8</b>
<b>11.2 Information supplied on the label</b> .....	<b>8</b>
<b>11.3 Constructional compatibility of components</b> .....	<b>8</b>
<b>11.4 Information for the patient</b> .....	<b>8</b>
<b>11.5 Marking</b> .....	<b>8</b>
<b>Annex A (informative) Evaluation of range of relative angular motion of components of fully constrained total knee joint replacement implants</b> .....	<b>9</b>
<b>Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC</b> .....	<b>10</b>