

Reclassification of Joint Implants

Directive 2005/50/EC

This Med-Info is addressed to

Manufacturers of hip, knee, and shoulder implants according to the EC Directive 93/42/EEC

Within the scope of Directive 2005/50/EC dated 11 August 2005, joint implants (hips, knees and shoulders) are classified as class III medical devices. In the past these products belonged to class IIb. Ancillary components such as screws, wedges, plates and instruments are not affected.

Manufacturers who have not yet classified their medical devices as class III or have subjected their class IIb products to type examination tests under Annex III and VI, have to reclassify their products and subject them to a conformity assessment under MDD Annex II.3 with Annex II.4 (Design Examination) or Annex III and V (Type Examination).

This directive has been in force since 1 September 2007.

New products placed on the market after 1 September 2007 have to follow conformity assessment procedures for class III products.

Transitional periods for complementary assessment procedures for already **existing class IIb products**:

	Products being assessed before 1 September 2007 :	
	Annex II.3	Annex III and VI
New/additional assessment procedure:	complementary assessment under Annex II.4 (design examination)	instead of Annex VI now under Annex V
Time limit for reclassification:	1 September 2009*	1 September 2010
Time limit for distribution of respective products to users:	1 September 2009	no restrictions

* At this, it should be considered that in the case of the conformity assessment procedure not yet being completed, the manufacturer will have to temporarily take the respective product out of the market after 1 September 2009 until the valid EC certificate is issued.

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What changes with regard to the technical documentation of manufacturers?

The previous conformity assessment procedures according to Annex II.3 will be complemented by Annex II.4.

Within the scope of the reclassification, detailed attestations of the following should be provided:

- mechanical safety
- performance data
- biocompatibility
- clinical data

Recommended Action

Due to the high number of products to be subjected to the reclassification, delays on the side of the Notified Bodies can occur with regard to the assessment procedures. You can help to avoid this by planning the reclassifications together with the Notified Body.

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