

Transposition Note for Commission Directive 2005/50/EC of 11 August 2005 on the reclassification of hip, knee and shoulder joint replacements in the framework of Council Directive 93/42/EEC concerning medical devices

The Medical Devices (Amendment) Regulations 2007 (“the Regulations”) do what is necessary to implement the Directive, including making consequential changes to domestic legislation to ensure its coherence in the area to which they apply

Articles	Objectives	Implementation	Responsibility
1	Requires Member States, by way of derogation from the reclassification rules set out in Annex IX to Council Directive 93/42/EEC (Directive 93/42), to provide that hip, knee and shoulder replacements are classified as class III medical devices	Regulations 2(a) and 5 of the Regulations amend regulations 2 and 7 of the Medical Devices Regulations 2002, so as to provide that devices in the UK are classified in accordance with Annex IX of Council Directive 93/42/EEC read with Commission Directive 2005/50/EC	Secretary of State
2	Defines “hip, knee or shoulder replacement” as meaning an implantable component part of a total joint replacement system which is intended to provide a function similar to that of either a natural hip joint, a natural knee joint or a natural shoulder joint. Ancillary components (i.e. screws wedges, plates and instruments) are excluded	Regulation 2(b) of the Regulations amends regulation 2 of the Medical Devices Regulations 2002, to insert the definition	Secretary of State

	from the definition		
3.1	<p>Provides for transitional arrangements for hip, knee and shoulder replacements that have undergone the conformity assessment procedure set out in Annex II to Directive 93/42 (full quality assurance), as it applied to Class IIb devices, before 1st September 2007. Such devices must be subject to a complementary conformity assessment under point 4 of Annex II leading to an EC design examination certificate before 1st September 2009. Alternatively, the manufacturer may apply for full conformity assessment for a Class III device under Annex III of Directive 93/42 (EC type-examination) with Annex IV (EC verification) or Annex V (production quality assurance).</p>	<p>Regulation 4 of the Regulations inserts a new regulation 4A of the Medical Devices Regulations 2002, to make transitional provisions for hip, knee and shoulder replacements.</p> <p>New regulation 4A(2) provides for the transitional arrangement involving a complementary conformity assessment under point 4 of Annex II to Directive 93/42.</p> <p>If a device undergoes a full conformity assessment for a Class III device, the product will be in compliance with regulation 13(4) of the Medical Devices Regulations 2002 and no further provision is required.</p>	Secretary of State
3.2	<p>Provides transitional arrangements for hip, knee and shoulder replacements that have been subject to a conformity assessment procedure under Annex III to Directive 93/42 (EC type-examination) with Annex VI (product quality assurance) before 1 September 2007. Such devices must be subject to the conformity assessment</p>	<p>Devices which have been subject to the procedures referred to in Article 3.2 will be in compliance with regulation 13(4) of the Medical Devices Regulations 2002 and no further provision is required</p>	Secretary of State

	<p>procedures for Class III devices before 1st September 2010: either-</p> <p>(a) the procedures under Annex III (EC type-examination) with Annex IV (EC verification) or Annex V (production quality assurance); or</p> <p>(b) the procedure relating to EC type-examination in Annex II.</p>		
3.3	<p>Member States will accept until 1 September 2009 the placing on the market and the putting into service of hip, knee and shoulder replacements covered by a decision of a notified body issued in accordance with Section 3.3 or 3.4 of Annex II to Directive 93/42 before 1 September 2007.</p>	<p>New regulation 4A(3) of the Medical Devices Regulations 2002, as inserted by regulation 4 of the Regulations, which has the effect that regulation 13(4) (which requires Class III devices to comply with the conformity assessment procedures for such devices) does not apply before 1st September 2009 to devices falling within Article 3.3.</p>	<p>Secretary of State</p>
3.4	<p>Member States will accept until 1 September 2010 the placing on the market and the putting into service of hip, knee and shoulder replacements covered by a decision of a notified body issued in accordance with Section 3.3 or 3.4 of Annex</p>	<p>New regulation 4A(4) of the Medical Devices Regulations 2002, as inserted by regulation 4 of the Regulations, has the effect that regulation 13(4) (which requires Class III devices to comply with the</p>	<p>Secretary of State</p>

	<p>VI to Directive 93/42 before 1 September 2007. In addition, Member States will permit such joint replacements to be put into service beyond that date.</p>	<p>conformity assessment procedures for such devices) does not apply before 1st September 2010 to devices falling within Article 3.4.</p> <p>New regulation 4A(5), as inserted by regulation 4 of the Regulations, provides that regulation 13A(4) does not apply to devices if they have been placed on the market before 1st September 2010 and are subsequently put into service.</p>	
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