STATUTORY INSTRUMENTS.

S.I. No. 92 of 2007

EUROPEAN COMMUNITIES (MEDICAL DEVICES) (RECLASSIFICATION OF HIP, KNEE AND SHOULDER JOINT REPLACEMENTS) (AMENDMENT) REGULATIONS 2007

(Prn. A7/0336)

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EUROPEAN COMMUNITIES (MEDICAL DEVICES) (RECLASSIFICATION OF HIP, KNEE AND SHOULDER JOINT REPLACEMENTS) (AMENDMENT) REGULATIONS 2007

I, MARY HARNEY, Minister for Health and Children, in exercise of the powers conferred on me by Section 3 of the European Communities Act, 1972, (No. 27 of 1972) and for the purpose of giving full effect to Council Directive 93/42/EEC of 14 June 1993 [1] and Commission Directive 2005/50/EC of 11 August 2005 [2] on the reclassification of hip, knee and shoulder joint replacements in the framework of Directive 93/42/EEC concerning medical devices, hereby make the following Regulations:

1. These Regulations may be cited as the European Communities (Medical Devices) (Reclassification of Hip, Knee and Shoulder Joint Replacements) (Amendment) Regulations 2007.

2. These Regulations shall come into force on 1 September 2007.

3. In these Regulations:

"Hip, knee or shoulder replacement" means 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 (screws, wedges, plates and instruments) are excluded from this definition;

"Principal Regulations" means the European Communities (Medical Devices) Regulations 1994 (S.I. No 252 of 1994).

4. By way of derogation from the Classification Criteria set out in Schedule 9 of the Principal Regulations, hip, knee and shoulder replacements shall be reclassified as medical devices falling within Class III.

5. Hip, knee and shoulder replacements that have been subject to a conformity assessment procedure pursuant to Article 9 (*a*) of the Principal Regulations before 1 September 2007 shall be subject to a complementary conformity assessment under Section 4 of Schedule 2 of the Principal Regulations leading to an EC design examination certificate before 1 September 2009. This provision does not preclude a manufacturer from submitting an application for conformity assessment based on Article 10 (*b*) of the Principal Regulations.

6. Hip, knee and shoulder replacements that have been subject to a conformity assessment procedure pursuant to Article 9 (*b*) (iii) of the Principal Regulations before 1 September 2007 may be subject to a conformity assessment as

[1]OJ No. L169, 12.7.1993
[2]OJ No. L210, 12.8.2005

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 6*th March*, 2007.

Class III medical devices pursuant to Article 10 (*b*) of the Principal Regulations before 1 September 2010. This provision does not preclude a manufacturer from submitting an application for conformity assessment based on Article 10 (*a*) of the Principal Regulations.

7. The placing on the market and the putting into service of hip, knee and shoulder replacements which are covered by a decision in accordance with Article 9 (*a*) of the Principal Regulations issued before 1 September 2007 shall be accepted until 1 September 2009.

8. The placing on the market of hip, knee and shoulder replacements which are covered by a decision in accordance with Article 9 (*b*) (iii) of the Principal Regulations issued before 1 September 2007 shall be accepted until 1 September 2010 and such total joint replacements can be permitted to be put into service beyond that date.

L.S.

GIVEN under my Official Seal
28 February 2007

MARY HARNEY
Minister for Health and Children

EXPLANATORY NOTE

(This note is not part of the Instrument and does not purport to be a legal interpretation)

These regulations amend the European Communities (Medical Devices) Regulations, 1994 (S.I. No. 252 of 1994) to give effect to Commission Directive 2005/50/EC of 11 August, 2005, as regards the reclassification of hip, knee and shoulder joint replacements to the higher classification of Class III medical devices.

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