

L.N. 113 of 2007

**PRODUCT SAFETY ACT
(CAP. 427)**

Medical Devices (Amendment) Regulations, 2007

IN exercise of the powers conferred by articles 38 to 40 of the Product Safety Act, 2001, the Minister for Competitiveness and Communications, on the advice of the Malta Standards Authority, has made the following regulations:—

1. (1) The title of these regulations is Medical Devices (Amendment) Regulations, 2007, and they shall be read and construed as one with the Medical Devices Regulations, 2003, hereinafter referred to as “the principal regulations”. Citation and commencement.
L.N. 47 of 2003.

(2) These regulations transpose Directive 2005/50/EC¹ of 11th August, 2005 on the reclassification of hip, knee and shoulder joint replacements in the framework of Council Directive 93/42/EEC² concerning medical devices.

(3) These regulations shall come into force on 1st September, 2007.

2. Immediately after regulation 1.2.4 of the principal regulations, there shall be inserted the following regulations: Amends regulation
1 of the principal
regulations.

“1.2.5. Hip, knee and shoulder replacements that have been subject to a conformity assessment procedure pursuant to regulation 8.3(a) of these regulations before 1st September, 2007, shall be subject to a complementary conformity assessment under point 4 of Schedule II to these regulations leading to an EC design examination certificate before 1st September, 2009.

¹ OJ No. L210, 12-08-2005, p. 41-43.

² OJ No. L210, 12-08-2005, p. 41.

(a) This provision does not preclude a manufacturer from submitting an application for conformity assessment based on regulation 8.1(b) of these regulations.

1.2.6. Hip, knee and shoulder replacements that have been subject to a conformity assessment procedure pursuant to regulation 8.3(b)(iii) of these regulations before 1st September, 2007, shall be subject to a conformity assessment as class III medical devices pursuant to regulation 8.1(b)(i) or (ii) of these regulations before 1st September, 2010.

(a) This provision does not preclude a manufacturer from submitting an application for conformity assessment based on regulation 8.1(a) of these regulations.

1.2.7. The placing on the market and the putting into service of hip, knee and shoulder replacements covered by the decision of the notified body issued in accordance with section 3.3 or 3.4 of Annex II of the Directive, which is set out in Schedule II to these regulations before 1st September, 2007, shall be accepted until 1st September, 2009.

1.2.8. The placing on the market of hip, knee and shoulder replacements which are covered by the decision of the notified body issued in accordance with section 3.3 or 3.4 of Annex VI of the Directive, which is set out in Schedule VI to these regulations before 1st September, 2007 shall be accepted until 1st September, 2010 and permitted to be put into service beyond this date.”.

Amends regulation
2 of the principal
regulations.

3. (1) For regulation 2.1.3 of the principal regulations, there shall be substituted the following:

“2.1.3. Devices shall be divided into Classes I, IIa, IIb and III. Classification shall be carried out in accordance with Annex IX of the Directive, which is set out in Schedule IX to these regulations.

2.1.3.1. By way of derogation from the rules set out in Annex IX of the Directive, which is set out in Schedule IX to these regulations, breast implants and hip, knee and shoulder joint replacements shall be reclassified as medical devices falling within Class III.”.

4. (1) Immediately after regulation 3.1.34 of the principal regulations, there shall be inserted the following:

Amends regulation
3 of the principal
regulations.

“3.1.35. “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.”.

