
STATUTORY INSTRUMENTS

2007 No. 400

The Medical Devices (Amendment) Regulations 2007

Amendment of regulation 2 of the principal Regulations

2. In regulation 2 of the principal Regulations (interpretation), in paragraph (1)—
- (a) after the definition of “Directive 2003/32” insert—

““Directive 2005/50” means 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(1);”;
 - (b) after the definition of “harmonised standard” insert—

““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, other than ancillary components (screws, wedges, plates and instruments);”.