## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations amend the Medical Devices Regulations 2002 ("the principal Regulations"), which contain the legislative measures necessary for the implementation of the European Community scheme for regulating the placing on the market and putting into service of medical devices. The amendments include amendments that are necessary for the implementation of Commission Directive 2003/12 of 3rd February 2003 on the reclassification of breast implants within the framework of Directive 93/42/EEC on medical devices ("Directive 2003/12") and Commission Directive 2003/32 of 23rd April 2003 on medical devices utilising tissues of animal origin ("Directive 2003/32").

Regulation 2 introduces new definitions into the principal Regulations, and amends another definition to take account of Directive 2003/32.

Regulation 5 requires breast implants to be reclassified as Class III devices, from Class IIb. Regulation 3(a) delays the effect of this reclassification by six months for products already on the market on 1st September 2003. Regulation 8 prevents notified bodies from extending earlier decisions on breast implants, taken on the basis that they were Class IIb devices, for longer than Directive 2003/12 allows.

Regulations 6, 7 and 9 set new conditions relating to the manufacture and supply of general medical devices manufactured utilising tissues of animal origin. Regulation 3(b) delays the application of these new requirements in relation to devices placed on the market before 1st April 2004.

Regulation 12 inserts a new definition for the purposes of Part V of the principal Regulations to ensure that the requirements relating to the incorrect marking of products cover all the products that may be incorrectly marked with a notified body number, conformity assessment body number or CE marking.

Regulation 13 amends the scheme for designating bodies as notified bodies to take account of the extension, by virtue of Directive 2003/32, of the tasks for which notified bodies may be designated, and regulation 16 makes a consequential amendment to the fees provisions.

Regulation 14 includes new obligations on notified bodies when evaluating devices manufactured utilising tissues of animal origin.

Regulation 2(a) and (f)—and also regulations 4, 10, 11, 15 and 17—correct drafting errors in the principal Regulations.

Regulatory Impact Assessments in relation to these Regulations, and a Transposition Note in relation to the implementation of Directives 2003/12 and 2003/32, have been placed in the libraries of both Houses of Parliament, and copies can be obtained from the Medicines and Healthcare products Regulatory Agency, Hannibal House, Elephant and Castle, London SE1 6TQ.

**Changes to legislation:**
There are currently no known outstanding effects for the The Medical Devices (Amendment) Regulations 2003.