STATUTORY INSTRUMENTS

# 2008 No. 2936

# The Medical Devices (Amendment) Regulations 2008

**Amendment of regulation 9 of the principal Regulations**

**6.** In regulation 9 of the principal Regulations (determining compliance of general medical devices with relevant essential requirements)—

(a) after paragraph (5), insert—

"(5A) When a custom-made device is supplied to a patient, the healthcare professional who writes the prescription for the custom-made device shall, in relation to each patient that they supply with such a device—

(a) ensure that the patient is aware that they may request the statement containing the information required by Sections 1 and 2 of Annex VIII; and

(b) ensure that the statement containing the information required by Sections 1 and 2 of Annex VIII is made available to the patient on request."; and

(b) after sub-paragraph (8) insert—

"(9) Where a device is intended by the manufacturer to be used in conjunction with both the provisions in Council Directive 89/686/EEC on the approximation or the laws of the Member States relating to personal protective equipment(**1**) and Directive 93/42, the relevant basic health and safety requirements of Directive 89/686/EEC shall also be fulfilled.".

(**1**) OJ No. L 399, 30.12.1989, p.18; as last amended by Regulation (EC) No. 1882/2003 (OJ No. L 284, 31.10.2003, p.1).