STATUTORY INSTRUMENTS

2002 No. 618

The Medical Devices Regulations 2002

PART II

General Medical Devices

Manufacturers etc. and conformity assessment procedures for general medical devices

17.—(1) A manufacturer of a relevant device or, where applicable, his authorised representative who is required to follow, or follows or has followed a conformity assessment procedure set out in Directive 93/42 shall observe the manufacturer's obligations set out in that procedure that apply to him.

(2) A manufacturer of a relevant device or, where applicable, his authorised representative shall, when following a conformity assessment procedure, take account of the results of any assessment or verification operations which have been carried out in accordance with Directive 93/42 at an intermediate stage of manufacture of the device.

(3) Where neither the manufacturer nor his authorised representative is established within the Community, the obligation to keep available the technical documentation referred to in—

(a) Section 6.3 of Annex II or Section 7.4 of Annex III shall fall upon the person responsible for placing on the market the device to which the documentation relates or, where appropriate, upon the importer referred to in Section 13.3(a) of Annex I;

(b) Section 2 of Annex VII shall fall upon the person who places on the market the device to which the documentation relates.