STATUTORY INSTRUMENTS

2002 No. 618

The Medical Devices Regulations 2002

PART VII

General, Enforcement and Miscellaneous

Designation etc. of authorised representatives

60.—(1) Where these Regulations place any obligation, other than an obligation referred to in regulation 17(3), on a manufacturer of a device or his authorised representative, and the manufacturer does not have a registered place of business in the Community or (where appropriate) in a State which is a Party to an Association Agreement, no person shall—

(a) place that device on the market; or

(b) supply that device in circumstances where it has been placed on the market,

unless the manufacturer of the device has designated an authorised representative to perform that obligation, but once the manufacturer has designated an authorised representative to perform that obligation, that obligation shall be performed by the authorised representative (although in all other cases it shall be performed by the manufacturer).

(2) If the manufacturer of a registrable device does not have a registered place of business in the Community or (where appropriate) in a State which is a Party to an Association Agreement, no person shall place that device on the market or supply that device in circumstances where it has been placed on the market unless its manufacturer has designated an authorised representative as—

(a) the person responsible for marketing the device in the Community; and

(b) the person responsible for registering in respect of that device with—

(i) the Secretary of State in accordance with regulation 19 or, as the case may be, 44, or

(ii) the competent authorities of another Member State or (where appropriate) a State which is a Party to an Association Agreement.

(3) Where a manufacturer of a registrable device, or of a relevant device that is not registrable, has designated an authorised representative as the person responsible for marketing the device within the Community, that authorised representative—

(a) may be proceeded against as a person placing the device on the market for the purposes of these Regulations;

(b) in relation to any supply of the device to a person within the United Kingdom after it has been placed on the market, may be proceeded against as a person supplying the device after it has been placed on the market, unless that supply is due to an act of another person established in the Community or in a State which is a Party to an Association Agreement.

(4) If a person claims or purports to act as an authorised representative of a manufacturer of a device, the Secretary of State may, for the purposes of enabling the Secretary of State to exercise his functions under these Regulations, require that person to furnish the Secretary of State with sufficient evidence that he is an authorised representative of the manufacturer.