STATUTORY INSTRUMENTS

2002 No. 618

The Medical Devices Regulations 2002

PART II

General Medical Devices

Procedures for systems and procedure packs, and for devices to be sterilised before use

14.—(1) Subject to paragraph (3), no person shall supply a system or procedure pack (if that supply is also a placing on the market, or if that supply is of a system or procedure pack that has been placed on the market) unless—

(a) the medical devices in that system or procedure pack are for use within their intended purpose and within the limits of use specified by their manufacturer;

(b) the person who places or has placed it on the market has drawn up a declaration that—

(i) he has verified the mutual compatibility of the medical devices in that system or procedure pack in accordance with the manufacturers' instructions, and he has carried out his operations in accordance with these instructions,

(ii) he has packaged the system or procedure pack and supplied relevant information to users incorporating relevant instructions from the manufacturers, and

(iii) his production of the system or procedure pack is subjected to appropriate methods of internal control and inspection,

and that declaration is true at the time it is made and continues to be true.

(2) Subject to paragraph (3), no person shall supply—

(a) a system or procedure pack which was sterilised before being placed on the market; or

(b) a relevant device (including a system or procedure pack) which is designed by its manufacturer to be sterilised before use,

(if that supply is also a placing on the market, or if that supply is of a device that has been placed on the market) unless the person who places, or who has placed, the device on the market satisfies the conditions set out in paragraph (4).

(3) Paragraphs (1) and (2)(a) shall only apply to a system or procedure pack if, by virtue of regulation 12(3), regulation 10 does not apply to that system or procedure pack.

(4) The conditions referred to in paragraph (2) are that the person shall—

(a) fulfil the obligations imposed by either Annex IV, Annex V or Annex VI that relate to the obtaining of sterility; and

(b) if the device has been sterilised, make a written declaration that sterilisation has been carried out in accordance with the manufacturer’s instructions.

(5) Where a conformity assessment procedure is carried out in respect of a relevant device (including a device which is a system or procedure pack) pursuant to this regulation—

(a) no person shall affix a CE marking to that device as a result of that procedure; and

(b) no person shall supply that device (if that supply is also a placing on the market, or if that supply is of a device that has been placed on the market) unless it is accompanied by the information referred to in Section 13 of Annex I, which shall include, where appropriate, the information supplied by the manufacturers of the devices which have been put together.

(6) The declarations referred to in paragraph (1)(b) and (4)(b) shall be kept available for the Secretary of State by the person responsible for placing the product on the market for a period of five years.