STATUTORY INSTRUMENTS

2002 No. 618

The Medical Devices Regulations 2002

PART II

General Medical Devices

Interpretation of Part II

5.—(1) In this Part, unless the context otherwise requires—

"accessory" means an article which, whilst not being a medical device, is intended specifically by its manufacturer to be used together with a medical device to enable it to be used in accordance with the use of the medical device intended by its manufacturer;

"custom-made device" means a relevant device that is—

(a) manufactured specifically in accordance with a written prescription of a duly qualified medical practitioner or a professional user which gives, under his responsibility, specific characteristics as to its design; and

(b) intended for the sole use of a particular patient,

but does not include a mass-produced product which needs to be adapted to meet the specific requirements of the medical practitioner or professional user;

"relevant device" shall be construed in accordance with regulation 6;

"single-use combination product" means a product which comprises a medical device and medicinal product forming a single integral product which is intended exclusively for use in the given combination and which is not reusable; and

"system or procedure pack" has the same meaning as in article 12 of Directive 93/42.

(2) In this Part, unless the context otherwise requires, a reference to a numbered article or Annex is to the article or Annex of Directive 93/42 bearing that number.