STATUTORY INSTRUMENTS

2002 No. 618

The Medical Devices Regulations 2002

PART III

Active Implantable Medical Devices

Interpretation of Part III

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

"custom-made device" means an active implantable medical device that is—

(a) manufactured specifically in accordance with a medical specialist's written prescription which gives, under his responsibility, specific characteristics as to its design; and

(b) intended to be used only for a particular patient; and

"relevant device" shall be construed in accordance with regulation 21.

(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 90/385 bearing that number.