STATUTORY INSTRUMENTS

2002 No. 618

The Medical Devices Regulations 2002

PART IV

In Vitro Diagnostic Medical Devices

Interpretation of Part IV

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

"accessory" means an article intended specifically by its manufacturer to be used together with an *in vitro* diagnostic medical device to enable that device to be used in accordance with its intended purpose, which is not—

(a) itself an *in vitro* diagnostic medical device;

(b) an invasive sampling medical device; or

(c) a medical device which is directly applied to the human body for the purpose of obtaining a specimen;

"calibration and control material" means any substance, material or article intended by its manufacturer either to establish measurement relationships or to verify the performance characteristics of a relevant device in conjunction with the intended use of that device;

"common technical specification" means a technical specification for a relevant device referred to in a list in Annex II which has been adopted in accordance with the procedure set out in article 7(2) and published in the Official Journal of the European Communities;

"device for self-testing" means an *in vitro* diagnostic medical device which is intended by its manufacturer to be able to be used by a member of the public in a home environment; and

"relevant device" shall be construed in accordance with regulation 33(1);

(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 98/79 bearing that number.