STATUTORY INSTRUMENTS

2002 No. 618

The Medical Devices Regulations 2002

PART IV

In Vitro Diagnostic Medical Devices

Determining compliance of *in vitro* diagnostic medical devices with relevant essential requirements

35.—(1) In determining which are the relevant essential requirements for a particular relevant device, and whether or not it complies with any of the relevant essential requirements, account shall be taken of its intended purpose.

(2) In order to meet the essential requirements set out in Section 8 of Part B of Annex I, the information to be provided under that Section must be in English if the device may reach a final user in the United Kingdom, unless—

(a) the Secretary of State, to the extent that Directive 98/79 allows him to do so, has authorised the use of another Community language or more than one other Community language; or

(b) the relevant device is a device for self-testing, in which case the instructions for use and the label must include a translation into the official language of any member State of the Community in which the device reaches a final user.

(3) A relevant device shall be presumed to comply with an essential requirement if it conforms as respects that requirement to a relevant national standard.

(4) A relevant device shall be treated as complying with an essential requirement in respect of which there is an applicable common technical specification only if it is in conformity with that specification or, if for duly justified reasons the manufacturer has not complied with that specification, an equivalent or higher specification.