
STATUTORY INSTRUMENTS

2002 No. 618

The Medical Devices Regulations 2002

PART IV

In Vitro Diagnostic Medical Devices

Essential requirements for *in vitro* diagnostic medical devices

34.—(1) Subject to regulation 39, no person shall place on the market or put into service a relevant device unless that device meets those essential requirements set out in Annex I which apply to it.

(2) Subject to regulation 39, no person shall supply a relevant device—

- (a) if that supply is also a placing on the market or putting into service of that device; or
- (b) in circumstances where that device has been placed on the market or put into service, unless that device meets those essential requirements set out in Annex I which apply to it.