STATUTORY INSTRUMENTS

2002 No. 618

The Medical Devices Regulations 2002

PART IV

In Vitro Diagnostic Medical Devices

Devices for performance evaluation

43. No person shall supply a device for performance evaluation (if that supply is also a making available of the device) unless the manufacturer or his authorised representative—

(a) has drawn up a statement containing the information required by Section 2 of Annex VIII and keeps that statement available for the Secretary of State for a minimum period of five years after the end of the performance evaluation;

(b) ensures that—

(i) the device conforms with the documentation mentioned in the said section 2, and

(ii) the relevant requirements of the Directive are complied with as respects that device; and

(c) undertakes to keep available, and keeps available, for the Secretary of State, for a minimum period of five years after the end of the performance evaluation, documentation allowing an understanding of the design, manufacture and performances of the device, including the expected performances, so as to allow assessment of conformity of the device with the requirements of these Regulations.