STATUTORY INSTRUMENTS

2002 No. 618

The Medical Devices Regulations 2002

PART IV

In Vitro Diagnostic Medical Devices

Manufacturers etc. and conformity assessment procedures for *in vitro* diagnostic medical devices

41.—(1) A manufacturer of a relevant device or, where applicable, his authorised representative who is required to follow, or follows or has followed a conformity assessment procedure set out in Directive 98/79 shall observe the manufacturer's obligations set out in that procedure that apply to him.

(2) A manufacturer of a relevant device or, where applicable, his authorised representative shall, when following a conformity assessment procedure, take account of the results of any assessment or verification operations which have been carried out in accordance with Directive 98/79 at an intermediate stage of manufacture of the device.

(3) A manufacturer or, where applicable, his authorised representative shall, in respect of any relevant device which the manufacturer has placed on the market or put into service, keep available for inspection by the Secretary of State—

(a) the declaration of conformity for that device;

(b) the technical documentation referred to in Annexes III to VIII relating to that device; and

(c) the decisions, reports and certificates of notified bodies relating to that device,

for a period ending five years after the manufacture of the last product.

(4) A person who in the course of manufacturing relevant devices or devices for performance evaluation removes, collects, or uses tissues, cells or substances of human origin shall, in the course of removing, collecting or using those tissues, cells or substances act in accordance with the principles laid down in the Convention of the Council of Europe for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine(**1**).

(5) Until the European databank referred to in article 12 has been established, the manufacturer or, where applicable, his authorised representative shall, in respect of any relevant device which the manufacturer has placed on the market in the United Kingdom, provide the Secretary of State with the data referred to in article 12(1)(a), and that data shall be provided in English.

(**1**) Council of Europe (ETSNo. 164), Orviedo, 4.4.1997.