STATUTORY INSTRUMENTS

1992 No. 2372

The Electromagnetic Compatibility Regulations 1992

PART II

APPLICATION

Apparatus wholly covered by other Directives

Medical devices

22.—(1) These Regulations do not apply to medical devices.

(2) In this regulation and regulation 3, "medical device " means any instrument, apparatus, appliance, material or other article, including software, whether used alone or in combination, intended by the manufacturer to be used for human beings solely or principally for the purpose of—

(a) diagnosis, prevention, monitoring, treatment or alleviation of disease, injury or handicap;

(b) investigation, replacement or modification of the anatomy or of a physiological process; or

(c) control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means, but excluding—

(i) an in vitro diagnostic device; and

(ii) an active implantable medical device;

and in this definition, "in vitro diagnostic device " means any device which is a reagent, reagent product, kit, instrument, equipment or system, whether used alone or in combination, intended by the manufacturer to be used solely or principally in vitro for the examination of substances derived from the human body with a view to providing information for the detection, diagnosis, control or treatment of a physiological state, of a state of health or disease, or of a congenital abnormality(**1**).

(**1**) The definitions of "medical device " and "in vitro diagnostic device " are those provided for in the Proposal for a Council Directive concerning medical devices (OJNo.C237, 12.9.91, p.3).