SCHEDULE 1

Amendment of the Medical Devices Regulations 2002

Amendment of regulation 2

2. In regulation 2 (interpretation)—

(a) for the definition of "authorised representative" substitute—

> ""authorised representative" means a person established within a relevant state, explicitly designated by the manufacturer who is not a person established in a relevant state, who acts for the manufacturer and may be addressed by authorities and bodies in a relevant state instead of the manufacturer with regard to the latter's obligation under Directive 90/385, Directive 93/42 and Directive 98/79;";

(b) in the definition of "EC CAB" omit "EC";

(c) in the definition of "intended for clinical investigation", in paragraph (b) for "Member State" substitute "relevant state";

(d) in the definition of "national standard" for "a Member State of the Community" substitute "a relevant state";

(e) in the definition of "placing on the market", for "the Community market" substitute "a relevant market";

(f) in paragraph (b) of the definition of "putting into service" for "the Community" substitute "a relevant state";

(g) in the appropriate places insert—

> ""relevant market" means a market of a relevant state;";
>
> ""relevant state" means—
>
> (a) in relation to any requirement relating to an *in vitro* diagnostic medical device, Northern Ireland or a Member State of the European Union;
>
> (b) in relation to any requirement relating to any other medical device, Northern Ireland or a state in the European Economic Area;
>
> (c) a State other than a Member State of the European Union which is a Party to an Association Agreement (where applicable under that Association Agreement);";
>
> ""UK mutual recognition agreement" means an agreement between the United Kingdom and another country that covers matters including the conditions under which the United Kingdom and that country will accept or recognise the results of the conformity assessment procedures undertaken by each other's designated bodies;";
>
> ""UK(NI) indication" means the marking in the form set out in Schedule 1 to the Product Safety and Metrology etc. (Amendment etc.) (UK(NI) indication) (EU Exit) Regulations 2020;";
>
> ""UK responsible person" is to be construed in accordance with regulation 19B(2) for the purposes of Part II, regulation 21C(2) for the purposes of Part III and regulation 44ZA(2) for the purposes of part IV.".