SCHEDULE 2

Amendments to EU tertiary legislation

PART 1

Amendments to Commission Decision 2002/364/EC

1. In Article 1 (which relates to the adoption of common technical specifications), at the end, insert "as that Annex applied before IP completion day and as modified by Schedule 2A to the Medical Devices Regulations 2002.".

2. Omit Article 2 (which relates to the addressees of the Decision).

3. In the Annex (which contains common technical specifications for in vitro diagnostic medical devices)—

(a) in point 3.1.4—

(i) for "CE marking" substitute "UK or CE marking",

(ii) for "CE marked" substitute "UK or CE marked";

(b) in point 3.1.8.—

(i) for "CE marked" substitute "UK or CE marked,",

(ii) for "notified body" substitute "approved body";

(c) in point 3.4.1—

(i) for "CE marking" substitute "UK or CE making",

(ii) for "CE marked" substitute "UK or CE marked";

(d) in Table 1, in the row marked Diagnostic sensitivity, for "Notified Body" in each place substitute "Approved Body".