SCHEDULE 2

Amendments to EU tertiary legislation

PART 1

Amendments to Commission Decision 2002/364/EC

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".