Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices

Article 5

Reference to standards

1 Member States shall presume compliance with the essential requirements referred to in Article 3 in respect of devices which are in conformity with the relevant national standards transposing the harmonised standards the reference numbers of which have been published in the *Official Journal of the European Communities*; Member States shall publish the reference numbers of such national standards.

2 If a Member State or the Commission considers that the harmonised standards do not entirely meet the essential requirements referred to in Article 3, the measures to be taken by the Member States with regard to these standards and the publication referred to in paragraph 1 of this Article shall be adopted by the procedure defined in Article 6(2).

3 Member States shall presume compliance with the essential requirements referred to in Article 3 in respect of devices designed and manufactured in conformity with common technical specifications drawn up for the devices in List A of Annex II and, where necessary, the devices in List B of Annex II. These specifications shall establish appropriate performance evaluation and re-evaluation criteria, batch release criteria, reference methods and reference materials.

The common technical specifications shall be adopted in accordance with the procedure mentioned in Article 7(2) and be published in the *Official Journal of the European Communities*.

Manufacturers shall as a general rule be required to comply with the common technical specifications; if for duly justified reasons manufacturers do not comply with those specifications they must adopt solutions of a level at least equivalent thereto.

Where, in this Directive, reference is made to harmonised standards, this is also meant to refer to the common technical specifications.