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

*Article 10*

**Registration of manufacturers and devices**

1 Any manufacturer who places devices on the market under his own name shall notify the competent authorities of the Member State in which he has his registered place of business:

— of the address of the registered place of business,

— of information relating to the reagents, reagent products and calibration and control materials in terms of common technological characteristics and/or analytes and of any significant change thereto including discontinuation of placing on the market; for other devices, the appropriate indications,

— in the case of devices covered by Annex II and of devices for self-testing, of all data allowing for identification of such devices, the analytical and, where appropriate, diagnostic parameters as referred to in Annex I, part A, section 3, the outcome of performance evaluation pursuant to Annex VIII, certificates and any significant change thereto, including discontinuation of placing on the market.

2 For devices covered by Annex II and for devices for self-testing, Member States may request to be informed of the data allowing identification together with the label and the instructions for use when such devices are placed on the market and/or put into service within their territory.

These measures cannot constitute a precondition for the placing on the market and/or putting into service of devices which are in conformity with this Directive.

3 Where a manufacturer who places devices on the market under his own name does not have a registered place of business in a Member State, he shall designate an authorised representative. The authorised representative shall notify the competent authorities of the Member State in which he has his registered place of business of all particulars as referred to in paragraph 1.

4 The notification referred to in paragraph 1 shall also include any new device. In addition, where, in the context of such notification, a device notified, bearing the CE marking, is a ‘new product’, the manufacturer shall indicate this fact on his notification.

For the purposes of this Article, a device is ‘new’ if:

a there has been no such device continuously available on the Community market during the previous three years for the relevant analyte or other parameter;

b the procedure involves analytical technology not continuously used in connection with a given analyte or other parameter on the Community market during the previous three years.

**[**[F1]5 Member States shall take all necessary measures to ensure that the notifications referred to in paragraphs 1 and 3 are registered immediately in the databank described in Article 12.

The procedures for implementing this Article and in particular those referring to the notification and the concept of significant change shall be adopted in accordance with the regulatory procedure referred to in Article 7(2).**]**

6 Transitionally, pending the establishment of a European databank accessible to the competent authorities of the Member States and containing the data relating to all devices available on the territory of the Community, the manufacturer shall give such notification to the competent authorities of each Member State concerned by the placing on the market.

**Textual Amendments**

**F1** Substituted by Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny Adaptation to the regulatory procedure with scrutiny — Part Four.