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

Article 8

Safeguard clause

1 Where a Member State ascertains that the devices referred to in Article 4(1), when correctly installed, maintained and used for their intended purpose may compromise the health and/or safety of patients, users or, where applicable, other persons, or the safety of property, it shall take all appropriate interim measures to withdraw such devices from the market or prohibit or restrict their being placed on the market or put into service. The Member State shall immediately inform the Commission of any such measures, indicating the reasons for its decision and, in particular, whether non-compliance with this Directive is due to:

a failure to meet the essential requirements referred to in Article 3;

b incorrect application of the standards referred to in Article 5, insofar as it is claimed that the standards have been applied;

c shortcomings in the standards themselves.

2 The Commission shall enter into consultation with the parties concerned as soon as possible. Where, after such consultation, the Commission finds that:

— the measures are justified, it shall immediately so inform the Member State which took the initiative and the other Member States; where the decision referred to in paragraph 1 is attributed to shortcomings in the standards, the Commission shall, after consulting the parties concerned, bring the matter before the committee referred to in Article 6(1) within two months if the Member State which has taken the decision intends to maintain it and shall initiate the procedures referred to in Article 6; where the measure referred to in paragraph 1 is attributed to problems related to the contents or to the application of the common technical specifications, the Commission shall, after consulting the parties concerned, bring the matter before the Committee referred to in Article 7(1) within two months,

— the measures are unjustified, it shall immediately so inform the Member State which took the initiative and the manufacturer or his authorised representative.

3 Where a non-complying device bears the CE marking, the competent Member State shall take appropriate action against whomsoever affixed the marking and shall inform the Commission and the other Member States thereof.

4 The Commission shall ensure that the Member States are kept informed of the progress and outcome of this procedure.