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

Article 18

Decisions in respect of refusal or restriction

1 Any decision taken pursuant to this Directive:

a to refuse or restrict the placing on the market or any making available or putting into service of a device, or

b to withdraw devices from the market,

shall state the exact grounds on which it is based. Such decisions shall be notified without delay to the partyconcerned, who shall at the same time be informed of the remedies available to him under the national law in force in the Member State in question and of the time limits to which such remedies are subject.

2 In the event of a decision as referred to in paragraph 1, the manufacturer or his authorised representative shall have an opportunity to put forward his point of view in advance, unless such consultation is not possible because of the urgency of the measure to be taken as justified in particular by public health requirements.