

RCN Policy and

has been raised about the lack of consistency in the application of the Directives across an EU th

- contact lenses
- implants for modification or fixation of body parts
- facial or other dermal or mucous membrane fillers
- equipment for liposuction
- invasive laser e

Previous Directives made provision for the regulation of self testing but the new regulations clarifies the position as to the specific safety and performance requirements of self testing kits. This includes a specific reference to instructions for self testing devices needing to provide information *(indeterminate result) on the test limitations and on the possibility of false positive or false negative results.* There is also a reference that *the information provided shall include a statement clearly directing that the user should not take any decision of medical relevance without first consulting a healthcare professional.*

The RCN supports self testing but such testing must be safe and effective for patients. The RCN also believes that it is vital that all users of self testing devices should be signposted to an appropriate healthcare professional if the result of the self test indicates such, i.e. a result that implies something is wrong or may be wrong once the result of the self test is known so that they can receive relevant health advice and treatment as necessary. **The RCN supports the reference**

and clear, with a focus on the national authorities following up should further information be required. Any reporting mechanism should complement manufacturers and national authorities own responsibilities for reporting serious incidents rather than replacing those responsibilities.

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