Notification of a Body in the framework of a technical harmonization directive

From : Department of Health Medicines and Healthcare Products Regulatory Agency (MHRA)
151 Buckingham Palace Road,
Victoria,
London SW1W 9SZ.
United Kingdom

To : **European Commission**
GROWTH Directorate-General
200 Rue de la Loi,
B-1049 Brussels.

Other Member States

Reference : Legislation : 98/79/EC In vitro diagnostic medical devices

Body name, address, telephone, fax, email, website :

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Body : **NB 0843**

The body is assessed according to :

In accordance with the In vitro Medical Devices Directive 98/79/EEC

The competence of the body was assessed by :

The assessment of the body covers the product categories and conformity assessment procedures concerned by this notification : Yes

Tasks performed by the Body :

Last approval date : 21/06/2007

Product family, product /Intended use/Product range	Procedure/Modules	Annexes or articles of the directives	Limitations
Self diagnosis devices for coagulation	EC declaration of conformity Full quality assurance system	Annex III Annex IV	
Self diagnosis devices for diabetes management, urine analysis, endocrinology, general biochemistry and general immunology	EC declaration of conformity	Annex III	
Self diagnosis devices for the determination of diabetes diagnosis and management, urine analysis, endocrinology, general biochemistry and chemsitry, and the determination of chlamydia infection and PSA	Full quality assurance system	Annex IV	