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

From : Department of Health Medicines and Healthcare products Regulatory Agency
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Victoria,
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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 0120**

Created : Unknown (Notifications pre-dating 2006 are not available in these lists) **| Last update :** 22/01/2013

Period of validity of the notification :

Valid until : Unlimited

The body is formally accredited against :

EN 45012 - EN ISO/IEC 17021

Name of National Accreditation Body (NAB) : UKAS - United Kingdom Accreditation Service

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

Tasks performed by the Body :

Created : 10/05/2011 **| Last update :** 18/05/2011

Product family, product /Intended use/Product range	Procedure/Modules	Annexes or articles of the directives	Limitations
*IVD 0100 - Reagents and reagent products, including related calibrators and control materials, for determining the following blood groups			
- *IVD 0101 - ABO system	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex IV Annex VII	
- *IVD 0102 - Rhesus (C, c, D, E, e)	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex IV Annex VII	
- *IVD 0103 - Anti-Kell	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex IV Annex VII	
*IVD 0200 - Reagents and reagent products, including related calibrators and control materials, for the detection, confirmation and quantification in human specimens of markers of			
- *IVD 0201 - HIV infection (HIV 1 and 2)	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex IV Annex VII	
- *IVD 0202 - HTLV I and II	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex IV Annex VII	
- *IVD 0203 - Hepatitis B, C and D	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex IV Annex VII	
*IVD 0300 - Reagents, reagent products and devices for self-diagnosis, including related calibrators and control materials, for determining, detection, quantification, diagnosing, evaluating			
- *IVD 0301 - Anti-Duffy and anti-Kidd	Full quality assurance system Production quality assurance	Annex IV Annex VII	
- *IVD 0302 - Irregular anti-erythrocytic antibodies	Full quality assurance system Production quality assurance	Annex IV Annex VII	
- *IVD 0303 - Congenital infections: rubella, toxoplasmosis	Full quality assurance system Production quality assurance	Annex IV Annex VII	
- *IVD 0304 - Hereditary disease: phenylketonuria	Full quality assurance system Production quality assurance	Annex IV Annex VII	
- *IVD 0305 - Human infections: cytomegalovirus, chlamydia	Full quality assurance system Production quality assurance	Annex IV Annex VII	
- *IVD 0306 - HLA tissue groups: DR, A, B	Full quality assurance system Production quality assurance	Annex IV Annex VII	
- *IVD 0307 - Tumoral marker: PSA	Full quality assurance system Production quality assurance	Annex IV Annex VII	
- *IVD 0308 - Risk of trisomy 21 (incl. software)	Full quality assurance system Production quality assurance	Annex IV Annex VII	
- *IVD 0309 - Device for self-diagnosis: device for the measurement of blood sugar	Full quality assurance system Production quality assurance	Annex IV Annex VII	
*IVD 0400 - Devices for self-testing			
- *IVD 0401 - Clinical chemistry	EC declaration of conformity Full quality assurance system Production quality assurance	Annex III Annex IV Annex VII	
- *IVD 0402 - Haematology	EC declaration of conformity Full quality assurance system Production quality assurance	Annex III Annex IV Annex VII	
- *IVD 0403 - Immunology	EC declaration of conformity	Annex III	

Product family, product /Intended use/Product range	Procedure/Modules	Annexes or articles of the directives	Limitations
	Full quality assurance system Production quality assurance	Annex IV Annex VII	
- *IVD 0405 - Pregnancy and ovulation	EC declaration of conformity Full quality assurance system Production quality assurance	Annex III Annex IV Annex VII	
- *IVD 0406 - Specimen receptacles	EC declaration of conformity Full quality assurance system Production quality assurance	Annex III Annex IV Annex VII	

Horizontal technical competence	Limitations
*MDS 7206 - IVDs in sterile condition	EC declaration of confirmity Annex III Full quality assurance system Annex IV Production quality assurance Annex VII
*MDS 7207 - IVDs utilising micromechanics	EC declaration of confirmity Annex III Full quality assurance system Annex IV Production quality assurance Annex VII
*MDS 7208 - IVDs utilising nanomaterials	EC declaration of confirmity Annex III Full quality assurance system Annex IV Production quality assurance Annex VII
*MDS 7209 - IVDs utilising biological active coating and/or material	EC declaration of confirmity Annex III Full quality assurance system Annex IV Production quality assurance Annex VII
*MDS 7210 - IVDs utilising material of human origin	EC declaration of confirmity Annex III Full quality assurance system Annex IV Production quality assurance Annex VII