

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

From : Department of Health Medicines
and Healthcare Products
Regulatory Agency (MHRA)
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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 0843

The body is formally accredited against :

EN ISO/IEC 17021 - Certification of management systems

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 :

Last approval date : 26/07/2018

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 verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex VI Annex IV Annex VII	
- *IVD 0102 - Rhesus (C, c, D, E, e)	EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex VI Annex IV Annex VII	
- *IVD 0103 - Anti-Kell	EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex VI 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 verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex VI Annex IV Annex VII	
- *IVD 0202 - HTLV I and II	EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex VI Annex IV Annex VII	
- *IVD 0203 - Hepatitis B, C and D	EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex VI 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	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex IV Annex VII	
- *IVD 0302 - Irregular anti-erythrocytic antibodies	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex IV Annex VII	
- *IVD 0303 - Congenital infections: rubella, toxoplasmosis	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex IV Annex VII	
- *IVD 0304 - Hereditary disease: phenylketonuria	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex IV Annex VII	
- *IVD 0305 - Human infections: cytomegalovirus, chlamydia	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex IV Annex VII	
- *IVD 0306 - HLA tissue groups: DR, A, B	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex IV Annex VII	

Product family, product /Intended use/Product range	Procedure/Modules	Annexes or articles of the directives	Limitations
- *IVD 0307 - Tumoral marker: PSA	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex IV Annex VII	
- *IVD 0308 - Risk of trisomy 21 (incl. software)	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex IV Annex VII	
- *IVD 0309 - Device for self-diagnosis: device for the measurement of blood sugar	EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex IV Annex VII	
*IVD 0400 - Devices for self-testing			
- *IVD 0401 - Clinical chemistry	EC declaration of conformity EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex III Annex IV Annex VII	
- *IVD 0402 - Haematology	EC declaration of conformity EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex III Annex IV Annex VII	
- *IVD 0403 - Immunology	EC declaration of conformity EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex III Annex IV Annex VII	
- *IVD 0404 - Molecular biology	EC declaration of conformity EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex III Annex IV Annex VII	
- *IVD 0405 - Pregnancy and ovulation	EC declaration of conformity EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex III Annex IV Annex VII	
- *IVD 0406 - Specimen receptacles	EC declaration of conformity EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex III Annex IV Annex VII	

Horizontal technical competence	Limitations
*MDS 7206 - IVDs in sterile condition	Including aseptic processing, ethylene oxide gas sterilization (EOG), low temperature steam and formaldehyde sterilization, moist heat sterilization, radiation sterilization (gamma, x-ray, electron beam), others (need to be specified)
*MDS 7210 - IVDs utilising material of human origin	