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

From : Ministero dello Sviluppo Economico - Direzione Generale per il Mercato, la Concorrenza, il Consumatore, la Vigilanza e la Normativa Tecnica
Via Sallustiana, 53
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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 0373**

The body is assessed according to :

EN ISO/IEC 17021 - Certification of management systems

EN ISO/IEC 17025 - Testing and calibration laboratories

EN ISO/IEC 17065 - Product certification

The competence of the body was assessed by : MINISTERO DELLA SALUTE - MINISTERO DELLO SVILUPPO ECONOMICO

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 : 19/04/2016

Product family, product /Intended use/Product range	Procedure/Modules	Annexes or articles of the directives	Limitations
*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)	Full quality assurance system EC type-examination Production quality assurance	Annex IV Annex V Annex VII	
- *IVD 0202 - HTLV I and II	Full quality assurance system EC type-examination Production quality assurance	Annex IV Annex V Annex VII	
- *IVD 0203 - Hepatitis B, C and D	EC type-examination EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex V 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 0303 - Congenital infections: rubella, toxoplasmosis	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex V Annex VI Annex IV Annex VII	
- *IVD 0305 - Human infections: cytomegalovirus, chlamydia	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex V Annex VI Annex IV Annex VII	
- *IVD 0307 - Tumoral marker: PSA	EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex V Annex VI Annex IV Annex VII	
*IVD 0400 - Devices for self-testing			
- *IVD 0401 - Clinical chemistry	EC declaration of conformity	Annex III	
- *IVD 0402 - Haematology	EC declaration of conformity	Annex III	
- *IVD 0403 - Immunology	EC declaration of conformity	Annex III	
- *IVD 0404 - Molecular biology	EC declaration of conformity	Annex III	
- *IVD 0405 - Pregnancy and ovulation	EC declaration of conformity	Annex III	
- *IVD 0406 - Specimen receptacles	EC declaration of conformity	Annex III	