

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
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To : **European Commission**
Enterprise Directorate-General
-
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

Created : Unknown (Notifications pre-dating 2006 are not available in these lists) | **Last update :** 29/06/2011

Period of validity of the notification :

Valid until : 31/12/2011(Expired/Withdrawn)

The body is assessed according to :

The competence of the body was assessed by : MINISTERO DELLA SALUTE

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

Tasks performed by the Body :

Created : 11/12/2009 | Last update : 29/06/2011

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	Full quality assurance system EC type-examination EC verification Production quality assurance	Annex IV Annex V Annex VI 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	Full quality assurance system EC type-examination EC verification Production quality assurance	Annex IV Annex V Annex VI Annex VII	
- *IVD 0305 - Human infections: cytomegalovirus, chlamydia	Full quality assurance system EC type-examination EC verification Production quality assurance	Annex IV Annex V Annex VI 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	