

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

**From :** Office of Health Authorisation and  
Administrative Procedures  
Zrínyi u. 3.,  
H-1051 Budapest  
Hungary

**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 :**

CE Certiso Orvos- és Kórháztechnikai Ellen#rz# és Tanúsító Kft.  
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**Body :**

**NB 2409**

**Created :** 20/06/2012 | **Last update :** 17/09/2012

**Period of validity of the notification :**

Valid until : 17/09/2015

**The body is assessed according to :**

NBOG DA HB

**The competence of the body was assessed by :** EEKH

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

## Tasks performed by the Body :

Created : 25/09/2012 | Last update : 25/09/2012

Product family, product /Intended use/Product range	Procedure/Modules	Annexes or articles of the directives	Limitations
*IVD 0300 - Reagents, reagent products and devices for self-diagnosis, including related calibrators and control materials, for determining, detection, quantification, diagnosing, evaluating			
- *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 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	
*MDS 7209 - IVDs utilising biological active coating and/or material	