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

From : National Institute of Pharmacy and Nutrition (OGYÉI)
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Hungary

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 :

NEOEMKI Nemzeti Orvostechnikai Eszköz Megfelel#ségértékel# és Tanúsító Korlátolt Felel#sség# Társaság (NEOEMKI LLC)
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Body : **NB 1011**

The body is assessed according to :

Directive 98/79/EC, national legislation 8/2003 (III. 13.) Decree of the Minister of Health, 18/2010 (IV. 20.) Decree of the Minister of Health, Designating Authorities Handbook and guidelines

The competence of the body was assessed by : National Institute of Pharmacy and Nutrition (OGYEI)

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 : 15/06/2020

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)	Annex IV	
- *IVD 0102 - Rhesus (C, c, D, E, e)	EC declaration of conformity (full quality assurance system)	Annex IV	
- *IVD 0103 - Anti-Kell	EC declaration of conformity (full quality assurance system)	Annex IV	
*IVD 0300 - Reagents, reagent products and devices for self-diagnosis, including related calibrators and control materials, for determining, detection, quantification, diagnosing, evaluating			
- *IVD 0302 - Irregular anti-erythrocytic antibodies	EC declaration of conformity (full quality assurance system)	Annex IV	
- *IVD 0307 - Tumoral marker: PSA	EC declaration of conformity (full quality assurance system)	Annex IV	
- *IVD 0308 - Risk of trisomy 21 (incl. software)	EC declaration of conformity (full quality assurance system)	Annex IV	
- *IVD 0309 - Device for self-diagnosis: device for the measurement of blood sugar	EC declaration of conformity (full quality assurance system)	Annex IV	
*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 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 7205 - IVDs incorporating software / utilising software / controlled by software	
*MDS 7206 - IVDs in sterile condition	Including aseptic processing, ethylene oxide gas sterilisation (EOG), low temperature steam and formaldehyde sterilisation, moist heat sterilisation, radiation sterilisation (gamma, x-ray, electron beam)
*MDS 7209 - IVDs utilising biological active coating and/or material	
*MDS 7210 - IVDs utilising material of human origin	