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

From : Ministry of Health
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Poland

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 1434**

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 : Minister of Health

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 : 12/08/2021

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 EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex III Annex V Annex VI Annex IV Annex VII	
- *IVD 0102 - Rhesus (C, c, D, E, e)	EC declaration of conformity EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex III Annex V Annex VI Annex IV Annex VII	
- *IVD 0103 - Anti-Kell	EC declaration of conformity EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex III Annex V 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 declaration of conformity EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex III Annex V Annex VI Annex IV Annex VII	
- *IVD 0202 - HTLV I and II	EC declaration of conformity EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex III Annex V Annex VI Annex IV Annex VII	
- *IVD 0203 - Hepatitis B, C and D	EC declaration of conformity EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex III Annex V 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 EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex III Annex V Annex VI Annex IV Annex VII	
- *IVD 0302 - Irregular anti-erythrocytic antibodies	EC declaration of conformity EC type-examination	Annex III Annex V	

Product family, product /Intended use/Product range	Procedure/Modules	Annexes or articles of the directives	Limitations
	EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex VI Annex IV Annex VII	
- *IVD 0303 - Congenital infections: rubella, toxoplasmosis	EC declaration of conformity EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex III Annex V Annex VI Annex IV Annex VII	
- *IVD 0304 - Hereditary disease: phenylketonuria	EC declaration of conformity EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex III Annex V Annex VI Annex IV Annex VII	
- *IVD 0305 - Human infections: cytomegalovirus, chlamydia	EC declaration of conformity EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex III Annex V Annex VI Annex IV Annex VII	
- *IVD 0306 - HLA tissue groups: DR, A, B	EC declaration of conformity EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex III Annex V Annex VI Annex IV Annex VII	
- *IVD 0307 - Tumoral marker: PSA	EC declaration of conformity EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex III Annex V Annex VI Annex IV Annex VII	
- *IVD 0308 - Risk of trisomy 21 (incl. software)	EC declaration of conformity EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex III Annex V Annex VI Annex IV Annex VII	
- *IVD 0309 - Device for self-diagnosis: device for the measurement of blood sugar	EC declaration of conformity EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex III Annex V Annex VI Annex IV Annex VII	
*IVD 0400 - Devices for self-testing			
- *IVD 0401 - Clinical chemistry	EC declaration of conformity EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex III Annex V Annex VI Annex IV Annex VII	
- *IVD 0402 - Haematology	EC declaration of conformity EC type-examination	Annex III Annex V	

Product family, product /Intended use/Product range	Procedure/Modules	Annexes or articles of the directives	Limitations
	EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex VI Annex IV Annex VII	
- *IVD 0403 - Immunology	EC declaration of conformity EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex III Annex V Annex VI Annex IV Annex VII	
- *IVD 0404 - Molecular biology	EC declaration of conformity EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex III Annex V Annex VI Annex IV Annex VII	
- *IVD 0405 - Pregnancy and ovulation	EC declaration of conformity EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex III Annex V Annex VI Annex IV Annex VII	
- *IVD 0406 - Specimen receptacles	EC declaration of conformity EC type-examination EC verification EC declaration of conformity (full quality assurance system) EC declaration of conformity (production quality assurance)	Annex III Annex V Annex VI Annex IV Annex VII	

Horizontal technical competence	Limitations
*MDS 7205 - IVDs incorporating software / utilising software / controlled by software	
*MDS 7206 - IVDs in sterile condition	
*MDS 7208 - IVDs utilising nanomaterials	
*MDS 7209 - IVDs utilising biological active coating and/or material	
*MDS 7210 - IVDs utilising material of human origin	