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

From : Czech Office for Standards, Metrology and Testing
Biskupský dvur 1148/5
110 00 Praha 1
Czech Republic

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 :

INSTITUT PRO TESTOVÁNI A CERTIFIKACI, a. s. (merged with ex-NB 1390)
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Body : **NB 1023**

The body is formally accredited against :

EN ISO/IEC 17021 - Certification of management systems

Name of National Accreditation Body (NAB) : CAI - Czech Accreditation Institute

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

Tasks performed by the Body :

Last approval date : 23/11/2020

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	Full quality assurance system EC type-examination Production quality assurance	Annex IV Annex V Annex VII	
- *IVD 0102 - Rhesus (C, c, D, E, e)	Full quality assurance system EC type-examination Production quality assurance	Annex IV Annex V Annex VII	
- *IVD 0103 - Anti-Kell	Full quality assurance system EC type-examination Production quality assurance	Annex IV Annex V 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)	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 Production quality assurance	Annex IV Annex V 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	Full quality assurance system EC type-examination EC verification Production quality assurance	Annex IV Annex V Annex VI Annex VII	
- *IVD 0302 - Irregular anti-erythrocytic antibodies	Full quality assurance system EC type-examination EC verification Production quality assurance	Annex IV Annex V Annex VI Annex VII	
- *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 0304 - Hereditary disease: phenylketonuria	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 0306 - HLA tissue groups: DR, A, B	Full quality assurance system EC type-examination EC verification Production quality assurance	Annex IV Annex V Annex VI Annex VII	
- *IVD 0307 - Tumoral marker: PSA	Full quality assurance system EC type-examination EC verification Production quality assurance	Annex IV Annex V Annex VI Annex VII	
- *IVD 0308 - Risk of trisomy 21 (incl. software)	Full quality assurance system EC type-examination	Annex IV Annex V	

Product family, product /Intended use/Product range	Procedure/Modules	Annexes or articles of the directives	Limitations
	EC verification Production quality assurance	Annex VI Annex VII	
- *IVD 0309 - Device for self-diagnosis: device for the measurement of blood sugar	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 Full quality assurance system EC type-examination EC verification Production quality assurance	Annex III Annex IV Annex V Annex VI Annex VII	
- *IVD 0402 - Haematology	EC declaration of conformity Full quality assurance system EC type-examination EC verification Production quality assurance	Annex III Annex IV Annex V Annex VI Annex VII	
- *IVD 0403 - Immunology	EC declaration of conformity Full quality assurance system EC type-examination EC verification Production quality assurance	Annex III Annex IV Annex V Annex VI Annex VII	
- *IVD 0404 - Molecular biology	EC declaration of conformity Full quality assurance system EC type-examination EC verification Production quality assurance	Annex III Annex IV Annex V Annex VI Annex VII	
- *IVD 0405 - Pregnancy and ovulation	EC declaration of conformity Full quality assurance system EC type-examination EC verification Production quality assurance	Annex III Annex IV Annex V Annex VI Annex VII	
- *IVD 0406 - Specimen receptacles	EC declaration of conformity Full quality assurance system EC type-examination EC verification Production quality assurance	Annex III Annex IV Annex V Annex VI Annex VII	

Horizontal technical competence	Limitations
*MDS 7206 - IVDs in sterile condition	
*MDS 7207 - IVDs utilising micromechanics	
*MDS 7208 - IVDs utilising nanomaterials	
*MDS 7209 - IVDs utilising biological active coating and/or material	
*MDS 7210 - IVDs utilising material of human origin	