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

From : Bundesministerium für
Gesundheit - Department
Pharmaceuticals and Medical
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To : **European Commission**
GROWTH Directorate-General
200 Rue de la Loi,
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Other Member States

Reference : Legislation : Regulation (EU) 2017/746 on in vitro diagnostic medical devices

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Body : **NB 2962**

Tasks performed by the Body :

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Product family, product /Intended use/Product range	Procedure/Modules	Annexes or articles of the directives	Conditions
I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE			
- 3. Devices intended to be used for markers of cancer and non-malignant tumours			
- IVR 0301 Devices intended to be used in screening, diagnosis, staging or monitoring of cancer	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI	
- IVR 0302 Other devices intended to be used for markers of cancer and non-malignant tumours	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI	
- 4. Devices intended to be used for human genetic testing			
- IVR 0401 Devices intended to be used in screening/confirmation of congenital/inherited disorders	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI	
- IVR 0402 Devices intended to be used to predict genetic disease/disorder risk and prognosis	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI	
- IVR 0403 Other devices intended to be used for human genetic testing	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI	
- 5. Devices intended to be used to determine markers of infections/immune status			
- IVR 0501 Devices intended to be used for pre-natal screening of women in order to determine their immune status towards transmissible agents	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI	
- IVR 0502 Devices intended to be used to detect the presence of, or exposure to transmissible agents in blood, blood components, cells, tissues or organs, or in any of their derivatives, to assess their suitability for transfusion, transplantation or cell administration	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI	
- IVR 0503 Devices intended to be used to detect the presence of, or exposure to an infectious agent including sexually transmitted agents	Conformity assessment based on a quality management system	Annex IX(I) Annex IX(II)	

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	Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex XI	
- IVR 0504 Devices intended to be used to determine the infectious load, to determine infective disease status or immune status and devices used for infectious disease staging	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI	
- IVR 0505 Devices intended to be used to grow/isolate/identify and handle infectious agents	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI	
- IVR 0506 Other devices intended to be used to determine markers of infections/immune status	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI	
- 6. Devices intended to be used for non-infectious pathologies, physiological markers, disorders/impairments (except human genetic testing), and therapeutic measures			
- IVR 0601 Devices intended to be used for screening/confirmation of specific disorders/impairments	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI	
- IVR 0602 Devices intended to be used for screening, determination or monitoring of physiological markers for a specific disease	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI	
- IVR 0603 Devices intended to be used for screening, confirmation/determination, or monitoring of allergies and intolerances	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI	
- IVR 0604 Other devices intended to be used for a specific disease	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI	
- IVR 0605 Devices intended to be used for monitoring of levels of medicinal products, substances or biological components	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(I) Annex IX(II) Annex XI	

Product family, product /Intended use/Product range	Procedure/Modules	Annexes or articles of the directives	Conditions
	Conformity assessment based on product quality assurance		
- IVR 0606 Devices intended to be used for non-infectious disease staging	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI	
- IVR 0607 Devices intended to be used for detection of pregnancy or fertility testing	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI	
- IVR 0608 Devices intended to be used for screening, determination or monitoring of physiological markers	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI	
- IVR 0609 Other devices intended to be used to define or monitor physiological status and therapeutic measures	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI	

Horizontal technical competence	Conditions
IVS 1001 Devices intended to be used for near-patient testing	
IVS 1002 Devices intended to be used for self-testing	
IVS 1003 Devices intended to be used as companion diagnostics	
IVS 1004 Devices manufactured utilising tissues or cells of human origin, or their derivatives	
IVS 1005 Devices in sterile condition	aseptic processing, ethylene oxide gas sterilisation (EOG), moist heat sterilisation, radiation sterilisation: gamma, radiation sterilisation: electron beam
IVS 1006 Calibrators (point 1.5 of Annex VIII to Regulation (EU) 2017/746)	
IVS 1007 Control materials with quantitative or qualitative assigned values intended for one specific analyte or multiple analytes (point 1.6 of Annex VIII to Regulation (EU) 2017/746)	
IVS 1008 Instruments, equipment, systems or apparatus	
IVS 1009 Software that are devices in themselves including software apps, software for data analysis, and for defining or monitoring therapeutic measures	
IVS 1010 Devices incorporating software/utilising software/controlled by software	
IVT 2001 In vitro diagnostic devices manufactured using metal processing	
IVT 2002 In vitro diagnostic devices manufactured using plastic processing	
IVT 2003 In vitro diagnostic devices manufactured using non-metal mineral processing (e.g. glass, ceramics)	
IVT 2004 In vitro diagnostic devices manufactured using non-metal non-mineral processing (e.g. textiles, rubber, leather, paper)	
IVT 2005 In vitro diagnostic devices manufactured using biotechnology	
IVT 2006 In vitro diagnostic devices manufactured using chemical processing	
IVT 2008 In vitro diagnostic devices manufactured in clean rooms and associated controlled environments	
IVT 2009 In vitro diagnostic devices manufactured using processing of materials of human, animal or microbial origin	

Horizontal technical competence	Conditions
IVT 2010 In vitro diagnostic devices manufactured using electronic components including communication devices	
IVT 2011 In vitro diagnostic devices which require packaging, including labelling	
IVP 3001 In vitro diagnostic devices which require knowledge regarding agglutination tests	
IVP 3002 In vitro diagnostic devices which require knowledge regarding biochemistry	
IVP 3003 In vitro diagnostic devices which require knowledge regarding chromatography	
IVP 3005 In vitro diagnostic devices which require knowledge regarding coagulometry	
IVP 3006 In vitro diagnostic devices which require knowledge regarding flow cytometry	
IVP 3007 In vitro diagnostic devices which require knowledge regarding immunoassays	
IVP 3008 In vitro diagnostic devices which require knowledge regarding lysis based testing	
IVP 3010 In vitro diagnostic devices which require knowledge regarding microscopy	
IVP 3011 In vitro diagnostic devices which require knowledge regarding molecular biological testing including nucleic acid assays and next generation sequencing (NGS)	
IVP 3012 In vitro diagnostic devices which require knowledge regarding physical chemistry including electrochemistry	
IVP 3013 In vitro diagnostic devices which require knowledge regarding spectroscopy	
IVD 4001 In vitro diagnostic devices which require knowledge regarding bacteriology	
IVD 4002 In vitro diagnostic devices which require knowledge regarding clinical chemistry/biochemistry	
IVD 4004 In vitro diagnostic devices which require knowledge regarding genetics	
IVD 4005 In vitro diagnostic devices which require knowledge regarding haematology/haemostasis, including coagulation disorders	
IVD 4007 In vitro diagnostic devices which require knowledge regarding immunohistochemistry/histology	
IVD 4008 In vitro diagnostic devices which require knowledge regarding immunology	
IVD 4009 In vitro diagnostic devices which require knowledge regarding molecular biology/diagnostics	
IVD 4012 In vitro diagnostic devices which require knowledge regarding virology	