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

From:
Finnish Medicins Agency
P.O. Box 55
FI-00034 FIMEA
Finland

To:
European Commission
GROWTH Directorate-General
200 Rue de la Loi,
B-1049 Brussels.

Other Member States

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

Body name, address, telephone, fax, email, website, MIC :

SGS FIMKO OY
Takomotie 8
00380 HELSINKI
Finland

+358 9 696 361
nb.fimko@sgs.com
www.sgs.fi

Body info: **NB 0598**

Tasks performed by the Body

Last approval date: 2025-10-21

Product	Procedures	Articles / Annexes	Conditions
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE -5. Devices intended to be used to determine markers of infections/immune status -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 type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex X Annex IX(I) Annex IX(II) Annex XI	
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE -7. Devices which are controls without a quantitative or qualitative assigned value -IVR 0702 Devices which are controls without a qualitative assigned value	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex X Annex IX(I) Annex IX(II) Annex XI	
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE -6. Devices intended to be used for non-infectious pathologies, physiological markers, disorders /impairments (except human genetic testing), and therapeutic measures -IVR 0603 Devices intended to be used for screening, confirmation/determination, or monitoring of allergies and intolerances	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex X Annex IX(I) Annex IX(II) Annex XI	
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE -5. Devices intended to be used to determine markers of infections/immune status -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 type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex X Annex IX(I) Annex IX(II) Annex XI	
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE -8. Class A devices in sterile condition -IVR 0803 Specimen receptacles referred to in point 2.5 (rule 5), under c), of Annex VIII to Regulation (EU) 2017/746	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex X Annex IX(I) Annex IX(II) Annex XI	

Product	Procedures	Articles / Annexes	Conditions
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE -6. Devices intended to be used for non-infectious pathologies, physiological markers, disorders /impairments (except human genetic testing), and therapeutic measures -IVR 0604 Other devices intended to be used for a specific disease	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex X Annex IX(I) Annex IX(II) Annex XI	
-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 type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex X Annex IX(I) Annex IX(II) Annex XI	
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE -6. Devices intended to be used for non-infectious pathologies, physiological markers, disorders /impairments (except human genetic testing), and therapeutic measures -IVR 0605 Devices intended to be used for monitoring of levels of medicinal products, substances or biological components	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex X Annex IX(I) Annex IX(II) Annex XI	
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE -6. Devices intended to be used for non-infectious pathologies, physiological markers, disorders /impairments (except human genetic testing), and therapeutic measures -IVR 0607 Devices intended to be used for detection of pregnancy or fertility testing	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex X Annex IX(I) Annex IX(II) Annex XI	
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE -4. Devices intended to be used for human genetic testing -IVR 0402 Devices intended to be used to predict genetic disease/disorder risk and prognosis	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex X Annex IX(I) Annex IX(II) Annex XI	

Product	Procedures	Articles / Annexes	Conditions
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE -4. Devices intended to be used for human genetic testing -IVR 0403 Other devices intended to be used for human genetic testing	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex X Annex IX(I) Annex IX(II) Annex XI	
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE -8. Class A devices in sterile condition -IVR 0801 Devices referred to in point 2.5 (rule 5), under a), of Annex VIII to Regulation (EU) 2017/746	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex X Annex IX(I) Annex IX(II) Annex XI	
-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 0302 Other devices intended to be used for markers of cancer and non-malignant tumours	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex X Annex IX(I) Annex IX(II) Annex XI	
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE -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 type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex X Annex IX(I) Annex IX(II) Annex XI	
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE -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 type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex X Annex IX(I) Annex IX(II) Annex XI	

Product	Procedures	Articles / Annexes	Conditions
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE -6. Devices intended to be used for non-infectious pathologies, physiological markers, disorders /impairments (except human genetic testing), and therapeutic measures -IVR 0602 Devices intended to be used for screening, determination or monitoring of physiological markers for a specific disease	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex X Annex IX(I) Annex IX(II) Annex XI	
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE -7. Devices which are controls without a quantitative or qualitative assigned value -IVR 0701 Devices which are controls without a quantitative assigned value	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex X Annex IX(I) Annex IX(II) Annex XI	
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE -8. Class A devices in sterile condition -IVR 0802 Instruments intended specifically to be used for in vitro diagnostic procedures referred to in point 2.5 (rule 5), under b), of Annex VIII to Regulation (EU) 2017/746	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex X Annex IX(I) Annex IX(II) Annex XI	
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE -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 type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex X Annex IX(I) Annex IX(II) Annex XI	

Product	Procedures	Articles / Annexes	Conditions
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE -5. Devices intended to be used to determine markers of infections/immune status -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 type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex X Annex IX(I) Annex IX(II) Annex XI	
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE -5. Devices intended to be used to determine markers of infections/immune status -IVR 0505 Devices intended to be used to grow/isolate /identify and handle infectious agents	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex X Annex IX(I) Annex IX(II) Annex XI	
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE -5. Devices intended to be used to determine markers of infections/immune status -IVR 0506 Other devices intended to be used to determine markers of infections/immune status	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex X Annex IX(I) Annex IX(II) Annex XI	
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE -6. Devices intended to be used for non-infectious pathologies, physiological markers, disorders /impairments (except human genetic testing), and therapeutic measures -IVR 0606 Devices intended to be used for non-infectious disease staging	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex X Annex IX(I) Annex IX(II) Annex XI	

Product	Procedures	Articles / Annexes	Conditions
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE **-6. Devices intended to be used for non-infectious pathologies, physiological markers, disorders /impairments (except human genetic testing), and therapeutic measures** **-IVR 0608 Devices intended to be used for screening, determination or monitoring of physiological markers**	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex X Annex IX(I) Annex IX(II) Annex XI	
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE **-6. Devices intended to be used for non-infectious pathologies, physiological markers, disorders /impairments (except human genetic testing), and therapeutic measures** **-IVR 0609 Other devices intended to be used to define or monitor physiological status and therapeutic measures**	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex X Annex IX(I) Annex IX(II) Annex XI	

Horizontal technical competences	Limitations
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:	
IVP 3001 In vitro diagnostic devices which require knowledge regarding agglutination tests:	

Horizontal technical competences	Limitations
IVP 3002 In vitro diagnostic devices which require knowledge regarding biochemistry:	
IVP 3003 In vitro diagnostic devices which require knowledge regarding chromatography:	
IVP 3004 In vitro diagnostic devices which require knowledge regarding chromosomal analysis:	
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:	
IVP 3014 In vitro diagnostic devices which require knowledge regarding tests of cell function:	
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), low temperature steam and formaldehyde sterilisation, moist heat sterilisation, radiation sterilisation (gamma, X-ray, electron beam), sterilisation with hydrogen peroxide, sterilisation with liquid chemical sterilising agents, thermic sterilisation with dry heat
IVS 1006 Calibrators (point 1.5 of Annex VIII to Regulation (EU) 2017 /746):	

Horizontal technical competences	Limitations
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 2007 In vitro diagnostic devices which require knowledge regarding the production of pharmaceuticals:	
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:	
IVT 2010 In vitro diagnostic devices manufactured using electronic components including communication devices:	
IVT 2011 In vitro diagnostic devices which require packaging, including labelling:	