Creation Date : 03/09/2020

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/746 on in vitro diagnostic medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
BSI Assurance UK Ltd Kitemark Court Davy Avenue Knowlhill Milton Keynes MK5 8PP United Kingdom	0086	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 I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE - 5. 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	
		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			Including 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

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
					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)			
		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			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		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			
		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 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			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		knowledge regarding lysis based testing			
		IVP 3009 In vitro diagnostic devices which require knowledge regarding measurement of radioactivity			
		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			
		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 4003 In vitro diagnostic devices which require knowledge regarding detection of transmissible agents (without organisms or viruses)			
		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			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		IVD 4006 In vitro diagnostic devices which require knowledge regarding histocompatibility and immunogenetics			
		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 4010 In vitro diagnostic devices which require knowledge regarding mycology			
		IVD 4011 In vitro diagnostic devices which require knowledge regarding parasitology			
		IVD 4012 In vitro diagnostic devices which require knowledge regarding virology			
TÜV SÜD Product Service GmbH Zertifizierstellen Ridlerstraße 65 80339 MÜNCHEN Germany	0123	I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE			
		- 1. Devices intended to be used for blood grouping			
		- - IVR 0101 Devices intended to determine markers of the ABO system [A (ABO1), B (ABO2), AB (ABO3)] I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE - 1. Devices intended to be used for blood grouping	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation	Annex X Annex IX(I) Annex IX(II) Annex XI	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			Conformity assessment based on product quality assurance		
		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			including: aseptic processing; etylene oxide gas sterilisation (EOG); low temperature steam and formaldehyde sterilisation; moist heat sterilisation; radiation sterilisation (gamma, x-ray, 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			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		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			
		IVP 3001 In vitro diagnostic devices which require knowledge regarding agglutination tests			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		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 3009 In vitro diagnostic devices which require knowledge regarding measurement of radioactivity			
		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			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		IVP 3014 In vitro diagnostic devices which require knowledge regarding tests of cell function			
		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 4003 In vitro diagnostic devices which require knowledge regarding detection of transmissible agents (without organisms or viruses)			
		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 4006 In vitro diagnostic devices which require knowledge regarding histocompatibility and immunogenetics			
		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 4010 In vitro diagnostic devices which require knowledge regarding mycology			
		IVD 4011 In vitro diagnostic devices which require knowledge regarding parasitology			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		IVD 4012 In vitro diagnostic devices which require knowledge regarding virology			
DEKRA Certification GmbH Handwerkstraße 15 70565 STUTTGART Germany	0124	I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE			
		- 1. Devices intended to be used for blood grouping			
		- - IVR 0101 Devices intended to determine markers of the ABO system [A (ABO1), B (ABO2), AB (ABO3)]	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(I) Annex IX(II)	
		- - IVR 0102 Devices intended to determine markers of the Rhesus system [RH1 (D), RHW1, RH2 (C), RH3 (E), RH4 (c), RH5 (e)]	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(I) Annex IX(II)	
		- - IVR 0103 Devices intended to determine markers of the Kell system [Kel1 (K)]	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(I) Annex IX(II)	
		- - IVR 0104 Devices intended to determine markers of the Kidd system [JK1 (Jka), JK2 (Jkb)]	Conformity assessment based on a quality management system Conformity assessment	Annex IX(I) Annex IX(II)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			based on assessment of technical documentation		
		- - IVR 0105 Devices intended to determine markers of the Duffy system [FY1 (Fya), FY2 (Fyb)]	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(I) Annex IX(II)	
		- - IVR 0106 Other devices intended to be used for blood grouping	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(I) Annex IX(II)	
		- 2. Devices intended to be used for tissue typing			
		- - IVR 0201 Devices intended to be used for tissue typing (HLA A, B, DR) to ensure the immunological compatibility of blood, blood components, cells, tissue or organs that are intended for transfusion or transplantation or cell administration	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(I) Annex IX(II)	
		- - IVR 0202 Other devices intended to be used for tissue typing	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(I) Annex IX(II)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- 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	Annex IX(I) Annex IX(II)	
		- - 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	Annex IX(I) Annex IX(II)	Markers for the predisposition of tumor diseases
		- 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	Annex IX(I) Annex IX(II)	
		- - 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	Annex IX(I) Annex IX(II)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- 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	Annex IX(I) Annex IX(II)	
		- 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	Annex IX(I) Annex IX(II)	
		- 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 Conformity assessment based on assessment of technical documentation	Annex IX(I) Annex IX(II)	
		- 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	Annex IX(I) Annex IX(II)	
		-	Conformity assessment	Annex IX(I)	limited to devices to be used to

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- IVR 0505 Devices intended to be used to grow/isolate/identify and handle infectious agents	based on a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(II)	identify and handle infectious agents
		- - 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	Annex IX(I) Annex IX(II)	
		- 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	Annex IX(I) Annex IX(II)	
		- - 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	Annex IX(I) Annex IX(II)	
		-	Conformity assessment	Annex IX(I)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- IVR 0603 Devices intended to be used for screening, confirmation/determination, or monitoring of allergies and intolerances	based on a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(II)	
		- - 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	Annex IX(I) Annex IX(II)	
		- - 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)	
		- - 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	Annex IX(I) Annex IX(II)	
		- - 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	Annex IX(I) Annex IX(II)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			technical documentation		
		- - 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	Annex IX(I) Annex IX(II)	
		- - 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	Annex IX(I) Annex IX(II)	
		- 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 a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(I) Annex IX(II)	
		- - IVR 0702 Devices which are controls without a qualitative assigned value	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(I) Annex IX(II)	
		- 8. Class A devices in sterile condition			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- 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 a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(I) Annex IX(II)	
		- 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 a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(I) Annex IX(II)	
		- 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 a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(I) Annex IX(II)	
		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			including: aseptic processing, ethylene oxide gas sterilisation (EOG), low temperature steam and

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
					formaldehyde sterilisation, moist heat sterilisation, radiation sterilisation (gamma, x-ray, electron beam), sterilisation with hydrogen peroxide, sterilisation with liquid chemical sterilising agens
		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)			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		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			
		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 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			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		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 3009 In vitro diagnostic devices which require knowledge regarding measurement of radioactivity			
		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			
		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 4003 In vitro diagnostic devices which require knowledge regarding detection of transmissible agents (without organisms or viruses)			
		IVD 4004 In vitro diagnostic devices which require knowledge regarding genetics			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		IVD 4005 In vitro diagnostic devices which require knowledge regarding haematology/haemostasis, including coagulation disorders			
		IVD 4006 In vitro diagnostic devices which require knowledge regarding histocompatibility and immunogenetics			
		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 4011 In vitro diagnostic devices which require knowledge regarding parasitology			
		IVD 4012 In vitro diagnostic devices which require knowledge regarding virology			
BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam Netherlands	2797	I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE			
		- 1. Devices intended to be used for blood grouping			
		- - IVR 0101 Devices intended to determine markers of the ABO system [A (ABO1), B (ABO2), AB (ABO3)] I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE - 1. Devices intended to be used for blood grouping	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(I) Annex IX(II)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- 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 I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE - 8. Class A devices in sterile condition	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	
		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			including aseptic processing, ethylene oxide gas sterilization (EOG), low temperature steam and formaldehyde sterilization, moist heat sterilization, radiation sterilization (gamma, x-ray, electron beam), sterilisation with hydrogen peroxide, sterilization with liquid chemical sterilizing agents, thermic sterilization with dry heat

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		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 2007 In vitro diagnostic devices which require knowledge regarding the production of pharmaceuticals			

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/746 on in vitro diagnostic medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		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			
		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 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 3009 In vitro diagnostic devices which require knowledge regarding measurement of radioactivity			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		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			
		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 4003 In vitro diagnostic devices which require knowledge regarding detection of transmissible agents (without organisms or viruses)			
		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 4006 In vitro diagnostic devices which require knowledge regarding histocompatibility and immunogenetics			

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/746 on in vitro diagnostic medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		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 4010 In vitro diagnostic devices which require knowledge regarding mycology			
		IVD 4011 In vitro diagnostic devices which require knowledge regarding parasitology			
		IVD 4012 In vitro diagnostic devices which require knowledge regarding virology			