MDCG 2021-14

Explanatory note on IVDR codes

July 2021

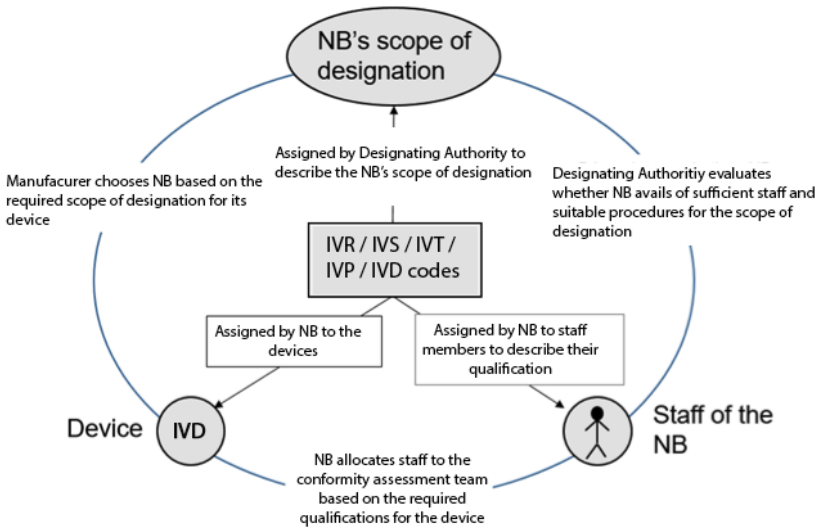
1 Introduction

Commission Implementing Regulation 2017/2185 establishes the codes for the designation of notified bodies in medical devices under Regulation (EU) 2017/745 and *in vitro* diagnostic medical devices under Regulation (EU) 2017/746. These codes are primarily used by designating authorities to define the notified body (NB) scope of designation but they are also used by the NB to:

1) describe the individual qualification of the NB's staff members

2) describe the qualification required for assessing a device.

It is acknowledged that these codes may be broad, furthermore, unequivocal authorisation of personnel to codes and the assignment of codes to a device may not always be straightforward. However, the NB's system needs to ensure, in all cases, that the authorisation of personnel and allocation of teams for the conformity assessment of a device ensures adequate knowledge and expertise.



2 Scope

The lists of codes and corresponding types of *in vitro* diagnostic medical devices (IVD) established by the above mentioned Regulation, namely, in its Annex II, takes into account various device types which can be characterised by design and intended purpose including companion diagnostics devices, devices for self-testing or for near patient testing, as well as by manufacturing processes and technologies used, such as sterilisation.

These lists of codes should be used in a way which allows a multi-dimensional application to all typology of devices. This will ensure that NB as well as the personnel assigned to conformity assessment are fully competent for the devices they are required to assess.

This guidance is intended to explain the different levels of codes and how they should be used, including the use of conditions to ensure a harmonised use of the codes especially for the allocation of resources to conformity assessment activities.

3 Assignment of codes to IVDs within the conformity assessment procedure

When a manufacturer lodges an application with a NB, the type of devices and technologies subject to conformity assessment activities are to be indicated. Usually, at the application review stage (as defined in section 4.3 of Annex VII IVDR), NB will verify the assignment of codes provided by the manufacturer or will assign these codes to the devices themselves. This verification is carried out in order to ensure that the NB is able to assess the application based on its designation, and that it has

available resources to carry out the relevant conformity assessment activities (feasibility evaluation). The final assignment is made by the NB.

After this application review, and signing of the contract, the NB will allocate appropriately qualified and authorised personnel to carry out audit activities or product reviews.[1]

The following table presents an overview of the different types of codes and a summary of the main characteristics of each of them for the assignment to specific devices and the allocation of resources.

Type Code	Assignment of codes to the device	Relevance for allocation of conformity assessment team
IVR **Codes reflect the design and intended purpose of the device**	Exactly 1 code per device.* The code should be selected according to the order in Regulation 2017/2185. If more than 1 IVR code is applicable, the one that is first in the list should be selected.	Allocation of personnel involved in the review of technical documentation (e.g. product reviewers) or in audits concerning product related aspects.
IVS **Horizontal codes that reflect the specific characteristics of the device**	0 to several per device. Assign all codes applicable to the device. Select once an IVR code has been assigned.	Allocation of personnel involved in the review of technical documentation. May also be applicable to **staff performing audits concerning** certain special processes.**
IVT **Horizontal codes that describe technologies**	1 to several per device Assign the codes which describe the main production technologies. Select once an IVR code has been assigned.	Allocation of personnel involved in audits (e.g. site auditors involved in the auditing of metal processing).
IVP **Horizontal codes that describe knowledge in examination procedures**	1 to several per device*** Assign the codes which describe the main examination procedures. Select once an IVR code has been assigned.	Allocation of personnel involved in the review of technical documentation.
IVD **Horizontal codes that describe knowledge in laboratory and clinical disciplines**	0 to several per device Assign the codes which describe the main laboratory and clinical disciplines. Select once an IVR code has been assigned.	Allocation of personnel involved in the review of technical documentation.

* Note: Cases may exist in which more than one IVR code is assigned (please refer to examples 1 and 2, section 3.1)

** Note: Assessment of these processes could be performed by product reviewers or site auditors depending on their competence and the NB's system

*** Note: Exceptional cases may exist that no IVP code is assigned (e.g. controls or specimen receptacles)

[1] The use of the codes in the sampling of technical documentation can be found in MDCG 2019-13: Guidance on sampling of MDR Class IIa / Class IIb and IVDR Class B/Class C devices for the assessment of the technical documentation.

3.1 IVR codes

IVR codes reflect the design and intended purpose of the device and hence are mostly relevant for the allocation of personnel involved in the review of technical documentation. In some specific cases, the NB may assign product reviewers to assess device performance and safety aspects during an audit. This means that if there are device related issues to be audited and the auditors do not possess the required qualification, product reviewers who are qualified for the device in question should be part of the audit team.

The NB needs to ensure that the personnel allocated to the project are competent to assess for the devices and technologies under assessment.

The IVR codes may specify a field of *in vitro* diagnostic medical application (e.g. IVR 0401 Devices intended to be used in screening/confirmation of congenital/inherited disorders). There are cases where more than one specific code might apply to a device. In addition, where there is a broad intended purpose, several codes may apply. Having these issues in mind, the codes were put in order such that the first applicable code in the list is the one to be selected. For example, when codes IVR 0201 and IVR 0202 both apply, the IVR 0201 code should be used. This approach ensures consistent assignment of codes (and therefore consistent assignment of suitably qualified staff) to devices.

Note that, given the complexity and the diversity of *in vitro* diagnostic medical devices, in exceptional cases deviations from the guidance given above may be necessary when assigning codes to devices in order to ensure suitably qualified staff in the conformity assessment. In such cases, a brief rationale shall be documented (see Example 1).

It is relatively common for IVD devices to be *'multiplexed'*. Such devices are composed of different "components". In the case of multiplexed devices, it may not be possible to define a main intended purpose or main technological principle. In many cases, such equally important components of multiplexed assays will still fall under the same code. Nevertheless, in some cases, the components of multiplexed assays would not fall under the same IVR code, if they were devices on their own. As the components may be considered equally important, a single code, selected from the first applicable code, cannot be assigned. In such an exceptional case, assignment of several IVR codes can be considered, if the properties and risks of the device cannot appropriately be covered with one IVR code alone, even in conjunction with the relevant IVS, IVT and IVD codes (see Example 2). Therefore, the NB needs to ensure that the assigned staff is qualified to assess all components of the device.

> Example 1: BRCA1 device intended for the detection of deletions or duplications in the human BRCA1 gene in order to confirm a potential cause and clinical diagnosis for hereditary breast and ovarian cancer and for molecular genetic testing of at-risk family members. According to the order mentioned above, this IVD falls into IVR 0300 codes. Nevertheless, additional competence regarding genetic testing would still be necessary (IVR 0400 codes). All relevant aspects may not be covered by one IVR code in conjunction with the relevant IVS, IVT, IVP and IVD codes.
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> Example 2: Multiplexed assay for gastrointestinal diseases/symptoms, combining assays for gastrointestinal pathogens with assays for digestive enzymes, immunochemical markers of food intolerances/sensitivities, markers of inflammation, or markers of gastric or colon cancers. This IVD may fall into IVR 0300, IVR 0500 and IVR 0600 codes. Use of several IVR codes is necessary to cover all aspects.

3.2 IVS codes

IVS codes are horizontal codes that are applicable to devices with specific characteristics. All codes that are applicable need to be assigned to a device in order to ensure that the review team possesses the full set of qualifications necessary for the conformity assessment. The IVS codes are primarily relevant for the allocation of personnel involved in the review of technical documentation. For some of the IVS codes the auditing aspects have their corresponding IVT code for the relevant technology (e.g. IVS 1004 Devices manufactured utilising tissues or cells of human origin, or their derivatives vs IVT 2009 *In vitro* diagnostic devices manufactured using processing of materials of human, animal and microbial origin). However, IVS codes may also be applicable to staff performing audits

concerning certain special processes (for example IVS 1005 for staff auditing ethylene oxide sterilisation processes).

Medical device software which are devices in their own right [2] including software apps, software for data analysis, and for defining or monitoring therapeutic measures should be assigned to code IVS 1009 in addition to the applicable IVR code which itself is dependent on the intended use or the field of application of the software. In case software is incorporated in a device, used by the device or controls the device the code IVS 1010 is relevant. The IVDR requires the definition of specific qualification criteria for personnel allocated to the assessment of software (see IVDR Annex VII, Section 3.2.2, 6th indent).

The same principle applies to control materials with quantitative or qualitative assigned values intended for one specific analyte or multiple analytes where the code IVS 1007 should be attributed in addition to the applicable IVR code which itself is dependent on the intended use of the device. Note: The codes IVR 0701 and 0702 are only appropriate for controls without a quantitative or qualitative assigned value, i.e. no other IVR code higher in the list of IVR codes can be selected.

Code IVS 1008 (instruments, equipment, systems or apparatus) should be used if the IVD contains, is part of or is integrated into instruments, equipment, systems or apparatus. Note: The code IVR 0802 only applies in case of separate sterile instruments of class A intended by the manufacturer specifically to be used for *in vitro* diagnostic procedures.

> Example: A blood glucose meter: An apparatus used for self-patient testing that contains an incorporated software to measure the glucose levels in the bloodstream will need to be assigned to the following IVS codes:
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> 1) IVS 1002 - Devices intended to be used for self-testing, because it is to be used directly by the end user,
>
> 2) IVS 1008 - Instruments, equipment, systems or apparatus, because it is an apparatus in itself,
>
> 3) IVS 1010 - Devices incorporating software/utilising software/controlled by software, because it contains software.

3.3 IVT codes

IVT codes relate to the technologies that are used in the manufacturing and making available of the devices. IVT codes are most relevant for the allocation of site auditors.

Assignment of IVT codes should be done taking into consideration the production of the device itself, in addition to critical upstream production steps. This means that, even though many codes could be applicable when taking into consideration the technologies/processes involved in the entire supply chain, related to manufacture, of a medical device, only those for the critical technologies/production steps should be considered.

> Example: An Immunoassay where the manufacturing involves antibody production, purification and immobilisation in a clean room/controlled environment should be assigned to at least the following IVT codes:
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> 1) IVT 2005 - In vitro diagnostic devices manufactured using biotechnology and
>
> 2) IVT 2008 - In vitro diagnostic devices manufactured in clean rooms and associated controlled environments.

Note that, despite the fact that the manufacturer itself may not physically manufacture all parts of the device, the IVT codes concerning the manufacturing steps are assigned to the device since they are relevant when auditing suppliers / subcontractors.

[2] Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR

3.4 IVP codes

IVP codes relate to the knowledge in examination procedures for the purpose of product verification. IVP codes are primarily used for the allocation of product reviewers.

> Example 1: Microorganism identification using latex agglutination beads to detect specific microorganism antigens. IVP 3001: In vitro diagnostic devices which require knowledge regarding agglutination tests
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> Example 2: Immune cell phenotyping (e.g. to determine acute myeloid leukaemia) by flow cytometry. IVP 3006: In vitro diagnostic devices which require knowledge regarding flow cytometry
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> Example 3: Electrolyte quantification using ion-selective electrodes. IVP 3012: In vitro diagnostic devices which require knowledge regarding physical chemistry including electrochemistry
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> Example 4: Microorganism identification using mass spectrometry IVP 3012: In vitro diagnostic devices which require knowledge regarding physical chemistry including electrochemistry
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> Example 5: Colorimetric assay for the quantification of creatinine.
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> 1) IVP 3002: In vitro diagnostic devices which require knowledge regarding biochemistry and
>
> 2) IVP 3013: In vitro diagnostic devices which require knowledge regarding spectroscopy

3.5 IVD codes

IVD codes relate to the knowledge in laboratory and clinical disciplines for the purpose of the product verification. IVD codes are relevant for the allocation of product reviewers.

The IVD codes listed in Commission Implementing Regulation 2017/2185 (IVD 4001 to 4012) refer to laboratory and clinical disciplines like bacteriology, clinical chemistry/biochemistry or immunology which specifically deal with or use the IVD in question. In addition, it may be necessary to involve experts of other clinical disciplines not listed in Commission Implementing Regulation 2017/2185 in which a disease or disorder to be detected with the IVD in question is treated (clinical specialists, see also e.g. IVDR Annex IX, 4.4). This may be the case, for example, when a marker for a disease is newly established by a manufacturer and the relevance of this marker for the underlying disease has to be assessed. Examples of these clinical disciplines may be cardiology or oncology.

4 Competence description: conditions (including limitations)

Conditions should be established by the NB for individual codes in cases where the qualification of the staff authorised to a certain code is not sufficient to cover the entire spectrum of the devices within this code. The designating authority could also apply conditions to the NB's designation where the NB does not have sufficient competence to cover a given code or could seek designation for conformity assessment of only certain devices within a code.

Conditions, including limitations, should be formulated in an unambiguous way. Furthermore, since the technical codes mirror the competence system of the NB, the conditions and limitations should concern device characteristics. The experience and competence of the NB may for example be limited due to the range of devices assessed under the IVDD. The limitations are applicable to all types of codes. Here, the focus is on examples of IVR codes as they serve as the basis of the technical documentation assessment.

> Example 1: IVR 0301: Devices intended to be used in screening, diagnosis, staging or monitoring of cancer. In cases where the experience is solely based on assessing devices for PSA, an appropriate condition could be including only PSA.

Example 2: IVR 0401: Devices intended to be used in screening/confirmation of congenital/inherited disorders. In cases where the experience is solely based on assessing devices for T21 risk, an appropriate condition could be including only devices for T21 risk.

Example 3: IVR 0505: Devices intended to be used to grow/isolate/identify and handle infectious agents. In cases where the full code cannot be covered due to lack of experience in, for example, growing and isolating viruses, a suitable condition could be either to:

- limit the scope to devices intended to identify infectious agents
- exclusion of devices intended for growing and isolating viruses.

Further examples of conditions are illustrated in the final column of the table below. Considerations of the conditions should be based on the demonstrated competence of the applicant body.

5 Specific clarifications linked to individual codes

IVR CODE	**Devices intended to be used to determine markers of the specific blood grouping systems to ensure the immunological compatibility of blood, blood components, cells, tissue or organs that are intended for transfusion or transplantation or cell administration**	**Devices covered[1] and Specific Considerations[2]**	**Examples of conditions**
IVR 0101	Devices intended to determine markers of the ABO system [A (ABO1), B (ABO2), AB (ABO3)]	ABO typing, cross matching and identifying antibodies against ABO antigens listed	
IVR 0102	Devices intended to determine markers of the Rhesus system [RH1 (D), RHW1, RH2 (C), RH3 (E), RH4 (c), RH5 (e)]	Rhesus typing, cross matching and identifying antibodies against Rhesus antigens listed	
IVR 0103	Devices intended to determine markers of the Kell system [Kel1 (K)]	Kell typing, cross matching and identifying antibodies against Kell antigens listed	
IVR 0104	Devices intended to determine markers of the Kidd system [JK1 (Jka), JK2 (Jkb)]	Kidd typing, cross matching and identifying antibodies against Kidd antigens listed	
IVR 0105	Devices intended to determine markers of the Duffy system [FY1 (Fya), FY2 (Fyb)]	Duffy typing, cross matching and identifying antibodies against Duffy antigens listed	
	Other devices intended to be used for blood grouping		
IVR 0106	Other devices intended to be used for blood grouping	Devices intended for other blood groups [e.g. MNS, Lewis, Anti-human globulin (Coombs serum)]	

[1] The devices included in this column are only some examples of the devices covered in the relevant code. This column is not intended to provide an exhaustive list of devices included in each code. The intended purpose of each device needs to be carefully considered in the application of the codes.

[2] The assessment should also consider Section 5.1 of Annex IX as well as validation of SSP acc. Article 29.

	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	Devices for typing, cross matching, identifying antibodies against listed HLA markers, relevant software, genetic screening and HLA CDC cross matching	
IVR 0202	Other devices intended to be used for tissue typing	Other devices for tissue typing, other HLA markers [e.g. HLA C, DPA1, DPB1, DQB1, Human Neutrophil Antigen (HNA)]	
	Devices intended to be used for markers of cancer and non-malignant tumours except devices for human genetic testing		
IVR 0301	Devices intended to be used in screening, diagnosis, staging or monitoring of cancer	Immunoassays for cancer associated antigens (CA 12-5, CA 15-3, CA 19-9, CEA, HE4, PSA) Faecal occult blood screening test (FOBT) and faecal immuno-chemical test (FIT) Image analysis algorithms related to detection and/or quantitation of cancer markers Device intended for BRCA1 genetic testing of tumour tissue to confirm a potential cause and clinical diagnosis for hereditary breast and ovarian cancer and for molecular genetic testing of at-risk family members	Limit only to PSA devices where the experience is solely based on assessing devices for PSA (see section 4)
IVR 0302	Other devices intended to be used for markers of cancer and non-malignant tumours	Companion diagnostic device for detection of somatic mutations in codons 12, 13 and 61 of the KRAS gene in human colorectal cancer (CRC) tumour tissue for determining eligibility for cetuximab or panitumumab treatment, devices (monoclonal antibodies) intended for the characterisation of hematologic neoplasia	
	Devices intended to be used for human genetic testing		
IVR 0401	Devices intended to be used in screening / confirmation of congenital / inherited disorders	Devices intended for prenatal screening for trisomy 13, 18, and 21; and related software Genetic test for mutations in NPC1 and NPC2 genes for diagnosis of Niemann–Pick disease, type C NGS test panel and related software for diagnosis of amyotrophic lateral	In cases where the experience is solely based on assessing devices for T21

		sclerosis (ALS)	risk, an appropriate condition could be including only devices for T21 risk (see section 4)
IVR 0402	Devices intended to be used to predict genetic disease/disorder risk and prognosis	Genetic testing for Cystic Fibrosis carriers Genetic testing for Alzheimer's and Parkinson's predictors (risk score) Genetic testing for diabetes and cardiovascular disease prognosis (risk scores) Software for calculating polygenic risk scores	
IVR 0403	Other devices intended to be used for human genetic testing	Whole exome sequencing for suspected genetic disorders where a specific genetic test is not available Pharmacogenomic testing for genes for CYP liver enzymes CYP2C9 and CYP2C19	
	Devices intended to be used for the screening, confirmation, identification of infectious agents or determination of 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	TORCH diagnostic: Antibodies (IgG, IgM) against rubella, toxoplasma Gondii, cytomegalovirus, herpes simplex Exclusion of molecular biology based devices or antigen detection devices as they detect the transmissible agent itself and not the antibodies against it	
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	Detection of viruses, bacteria, parasites or non-conventional infectious agents (e.g. vCJD) Immunological (detection of Ab and/or Ag) and molecular biology assays	
IVR 0503	Devices intended to be used to detect the presence of, or exposure to an infectious agent including sexually transmitted agents	Tests for any infectious agent (bacteria, fungi, parasites, mycobacteria, viruses) using all possible direct and indirect methods (e.g. immunological assays, molecular biology assays, staining, histological assays)	

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	NAT for measuring viral load for HIV, measurement of tetanus Ab (protective level against tetanus) Including antigenic assays if they are quantitative Devices used to identify and enumerate TBNK cells (CD4) for monitoring some forms of immune deficiency and autoimmune disease and to monitor HIV individuals	
IVR 0505	Devices intended to be used to grow / isolate / identify and handle infectious agents	Agar plate, liquid culture media, preservation media, minimal inhibition concentration (MIC) tests	A suitable condition could be either to: limit the scope to devices intended to identify infectious agents, exclusion of devices intended for growing and isolating viruses (see section 4).
IVR 0506	Other devices intended to be used to determine markers of infections / immune status	Non-specific markers of sepsis (e.g. C-reactive protein, procalcitonin)	
	Devices intended to be used for a specific disease		
IVR 0601	Devices intended to be used for screening / confirmation of specific disorders / impairments	Devices for exploration of kidney disorder or liver injury	
IVR 0602	Devices intended to be used for screening, determination or monitoring of physiological markers for a specific disease	Measurement of clotting factors for specific diseases (e.g. von Willebrand factor, factor VIII for haemophilia A), haemoglobin A1c for diabetes monitoring	
IVR 0603	Devices intended to be used for screening, confirmation / determination, or monitoring of allergies and intolerances	IgE specific immunoassays, IgA anti-transglutaminase (coeliac disease)	
IVR 0604	Other devices intended to be used for a specific disease	Other devices not falling into the codes above	

	Devices intended to be used to define or monitor physiological status and therapeutic measures		
IVR 0605	Devices intended to be used for monitoring of levels of medicinal products, substances or biological components	Medicinal product, or poison toxic products measurement or detection in blood (e.g lithium, warfarin, valproïc acid) or in urine (e.g. benzodiazepin)	
IVR 0606	Devices intended to be used for non-infectious disease staging	Cholesterol, hormone measurement (estradiol progesterone, TSH, aldosterone)	
IVR 0607	Devices intended to be used for detection of pregnancy or fertility testing	HCG, LH, estradiol (depending of the intended use)	
IVR 0608	Devices intended to be used for screening, determination or monitoring of physiological markers	Urine or blood markers: magnesium, potassium, coagulation rate, INR, partial thromboplastin time (PTT), platelet count, platelet	
IVR 0609	Other devices intended to be used to define or monitor physiological status and therapeutic measures	Other devices not falling into the codes above	
	Controls without a quantitative or qualitative assigned value		
IVR 0701	Devices which are controls without a quantitative assigned value	Any IVD controls that are qualitative (e.g. control materials for detection of pathogens)	
IVR 0702	Devices which are controls without a qualitative assigned value	Any IVD controls that do not fall under IVR 0701 (e.g. QC material as a heterozygous quality control to monitor analytical performance of the extraction, amplification and detection) A DNA or RNA probe supplied for use as a non-assay specific normal control for in situ hybridisation (ISH)	
	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	Products for general laboratory use, accessories which possess no critical characteristics, buffer solutions, washing solutions, and general culture media and histological stains, intended by the manufacturer to make them suitable for in vitro diagnostic procedures relating to a specific examination (e.g. kits for isolation and purification of nucleic acids from human specimens, sterile buffer solutions, lysing solutions and diluents specified for use with an IVD)	
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	Sterile instruments intended by the manufacturer specifically to be used for in vitro diagnostic procedures	
IVR 0803	Specimen receptacles referred to in point 2.5 (rule 5), under c), of Annex VIII to Regulation (EU) 2017/746	Specimen receptacles for e.g. blood, urine	

IVS CODE	In vitro diagnostic devices with specific characteristics	Devices covered and Specific Considerations	Examples of conditions
IVS 1001	Devices intended to be used for near-patient testing	Troponin tests used in emergency room, blood glucose meter, blood grouping devices used for pre-transfusion control Depending on the intended use, devices may be classified into IVS 1001 or 1002 or both. Also depending on national regulations	
IVS 1002	Devices intended to be used for self-testing	Pregnancy and fertility self-tests, HIV self-test, blood glucose meters	
IVS 1003	Devices intended to be used as companion diagnostics	A companion diagnostic device provides information that is essential for the safe and effective use of a corresponding therapeutic product (e.g. used for the selection of therapeutic products, used for the treatment of cancers, for determination of hypersensitivity to anti-retroviral drugs)	
IVS 1004	Devices manufactured utilising tissues or cells of human origin, or their derivatives	Red blood cells as control for blood grouping	
IVS 1005	Devices in sterile condition	Blood or pathogens collection tubes and handling devices for pathogens (HPV collection tube)	
IVS 1006	Calibrators (point 1.5 of Annex VIII to Regulation (EU) 2017/746)	Calibrators sold separately from the measurement device (calibrators for blood glucose meters)	
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)	Multi-analyte controls (anti-HIV, anti-HTLV, anti-HBc, anti-HCV, anti-CMV anti-treponema pallidum, and HBsAg), single analyte control (Factor II or Factor V positive control for NAT assays)	
IVS 1008	Instruments, equipment, systems or apparatus	IVD analysers	
IVS 1009	Software that are devices in themselves including software apps, software for data analysis, and for defining or monitoring therapeutic measures	Software for sickle cell disease screening in newborns, software for hepatic fibrosis determination	
IVS 1010	Devices incorporating software / utilising software / controlled by software	Blood glucose meter	

IVT CODE	In vitro diagnostic devices for which specific technologies are used	Examples of device manufacturing technologies
IVT 2001	In vitro diagnostic devices manufactured using metal processing	Stainless steel balls of grinding tubes, analyser with metal parts
IVT 2002	In vitro diagnostic devices manufactured using plastic processing	Plastic cassettes of rapid tests, plastic tubes for blood collection
IVT 2003	In vitro diagnostic devices manufactured using non-metal mineral processing (e.g. glass, ceramics)	Glass tubes for blood collection or containing grow media
IVT 2004	In vitro diagnostic devices manufactured using non-metal non-mineral processing (e.g. textiles, rubber, leather, paper)	Weaving, knitting, printing
IVT 2005	In vitro diagnostic devices manufactured using biotechnology	Antibody or other protein production and purification technologies Coating of ELISA plates and microarrays with biomolecules
IVT 2006	In vitro diagnostic devices manufactured using chemical processing	Manufacturing of reagents, chemical labelling
IVT 2007	In vitro diagnostic devices which require knowledge regarding the production of pharmaceuticals	Production, handling and incorporation into an IVD of substances which, if used separately, can be considered to be a medicinal product
IVT 2008	In vitro diagnostic devices manufactured in clean rooms and associated controlled environments	Aseptic filling of culture media
IVT 2009	In vitro diagnostic devices manufactured using processing of materials of human, animal or microbial origin	Handling, dissection, storage, processing, inactivation and sterilisation of human and animal tissues, sourcing
IVT 2010	In vitro diagnostic devices manufactured using electronic components including communication devices	Software related to trisomy risk/PSA/blood glucose/pregnancy/ovulation
IVT 2011	In vitro diagnostic devices which require packaging, including labelling	IVDs in sterile condition, packaging for light sensitive reagents

IVP CODE	In vitro diagnostic devices which require specific knowledge in examination procedures	Devices covered and specific conditions	Examples of conditions
IVP 3001	In vitro diagnostic devices which require knowledge regarding agglutination tests	Microorganism identification, blood typing including latex agglutination	
IVP 3002	In vitro diagnostic devices which require knowledge regarding biochemistry	Creatinine, lactate	
IVP 3003	In vitro diagnostic devices which require knowledge regarding chromatography	Vitamin D analysed by HPLC, therapeutic drug monitoring by LC-MS/MS	
IVP 3004	In vitro diagnostic devices which require knowledge regarding chromosomal analysis	Chromosome staining, FISH (in combination with microscopy), chromosome painting, comparative genetic hybridisation	
IVP 3005	In vitro diagnostic devices which require knowledge regarding coagulometry	PT/INR	
IVP 3006	In vitro diagnostic devices which require knowledge regarding flow cytometry	Immunophenotyping by flow cytometry	
IVP 3007	In vitro diagnostic devices which require knowledge regarding immunoassays	ELISA, LFIA	
IVP 3008	In vitro diagnostic devices which require knowledge regarding lysis based testing	Euglobulin lysis	
IVP 3009	In vitro diagnostic devices which require knowledge regarding measurement of radioactivity	Radioimmunoassays	
IVP 3010	In vitro diagnostic devices which require knowledge regarding microscopy	Sediment analysis of urine, cell staining	
IVP 3011	In vitro diagnostic devices which require knowledge regarding molecular biological testing including nucleic acid assays and next generation sequencing (NGS)	Huntington's, BRCA1/2	Limited when lack of NGS knowledge
IVP 3012	In vitro diagnostic devices which require knowledge regarding physical chemistry including electrochemistry	Electrolytes, glucose detection using electrochemical methods, mass spectrometry	
IVP 3013	In vitro diagnostic devices which require knowledge regarding spectroscopy	Absorption, fluorescence, scattering	
IVP 3014	In vitro diagnostic devices which require knowledge regarding tests of cell function	Lymphocyte function	

IVD CODE	In vitro diagnostic devices which require specific knowledge in laboratory and clinical disciplines for the purpose of product verification	Devices covered and specific conditions	Examples of conditions
IVD 4001	In vitro diagnostic devices which require knowledge regarding bacteriology	Culture medias, devices for identification, detection or measurement of bacteria	
IVD 4002	In vitro diagnostic devices which require knowledge regarding clinical chemistry / biochemistry	Non-automated devices and clinical chemistry analysers (single or multi-parameters)	
IVD 4003	In vitro diagnostic devices which require knowledge regarding detection of transmissible agents (without organisms or viruses)	CJD, vCJD and other devices for non-conventional organism detection if available	
IVD 4004	In vitro diagnostic devices which require knowledge regarding genetics	Devices using nucleic acid-based technologies (NAT) such as PCR, RT-PCR, sequencing, LAMP and DNA/RNA microarrays, microRNA analysis, clinical epigenetics methods	
IVD 4005	In vitro diagnostic devices which require knowledge regarding haematology / haemostasis, including coagulation disorders	Cell counts, haemoglobin, PT/INR, Factor V	
IVD 4006	In vitro diagnostic devices which require knowledge regarding histocompatibility and immunogenetics	Blood and tissue typing/compatibility, autoimmune conditions	
IVD 4007	In vitro diagnostic devices which require knowledge regarding immunohistochemistry / histology	Synaptophysin staining for diagnosis of neuroendocrine neoplasms, ICH or FISH for HER2 in breast cancer diagnostics	
IVD 4008	In vitro diagnostic devices which require knowledge regarding immunology	Anti-dsDNA, anti-Sm and ANA antibodies, vaccine antibody test and antibody deficiency tests	
IVD 4009	In vitro diagnostic devices which require knowledge regarding molecular biology / diagnostics	Devices using nucleic acid-based technologies (NAT) such as PCR, RT-PCR, sequencing, genotyping, LAMP and DNA/RNA microarrays, microRNA analysis, clinical epigenetics methods	
IVD 4010	In vitro diagnostic devices which require knowledge regarding mycology	Assays for fungal infections	
IVD 4011	In vitro diagnostic devices which require knowledge regarding parasitology	Assays for parasitic infections	
IVD 4012	In vitro diagnostic devices which require knowledge regarding virology	Assays for viral infections and measurement of viral titers	