

## **MDCG 2021- 18**

### **Applied-for scope of designation and notification of a Conformity Assessment Body Regulation (EU) 2017/746 (IVDR)**

**July 2021**

This document has been endorsed by the Medical Device Coordination Group (MDCG) established by Article 103 of Regulation (EU) 2017/745. The MDCG is composed of representatives of all Member States and it is chaired by a representative of the European Commission.

The document is not a European Commission document and it cannot be regarded as reflecting the official position of the European Commission. Any views expressed in this document are not legally binding and only the Court of Justice of the European Union can give binding interpretations of Union law.

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applicable for  MDR  IVDR

## Applied-for scope of designation and notification of a Conformity Assessment Body – Regulation (EU) 2017/746 (IVDR)<sup>1</sup>

Name of the national authority responsible for notified bodies (DA)	
Name of the applicant conformity assessment body (CAB) and, if applicable, notified body's identification number <sup>2</sup>	
Address of the CAB	
Date of application	

### I CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE

Please mark the selected types of products and conformity assessment activities with a cross (X) in the grey coloured columns below. The different lists of codes are in accordance with the Implementing Regulation on the list of codes<sup>3</sup>. Conformity assessment activities are identified by the corresponding reference to the Annex of the IVDR.

<sup>1</sup> This document was endorsed by MDCG and published as NBOG F 2017-4 in its first version in February 2018. Based on experience gained in the context of the joint assessment process, the document has been updated and its revision published as MDCG document.

<sup>2</sup> In case of a new applicant, please insert « new »

<sup>3</sup> [Commission Implementing Regulation](#) (EU) 2017/2185 of 23 November 2017 on the list of codes and corresponding types of devices for the purpose of specifying the scope of the designation as notified bodies in the field of medical devices under Regulation (EU) 2017/745 of the European Parliament and of the Council and in vitro diagnostic medical devices under Regulation (EU) 2017/746 of the European Parliament and of the Council

The products and activities selected below will constitute the applied-for scope of application and therefore should be linked to the conformity assessment body's competence. Conditions, such as limitations must be included when applicable (e.g. when the competence cannot be justified for the whole code).

### 1. Devices intended to be used for blood grouping

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	Annexes				Conditions
		IX(I)	IX(II)	X	XI	
IVR 0101	Devices intended to determine markers of the ABO system [A (ABO1), B (ABO2), AB (ABO3)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
IVR 0102	Devices intended to determine markers of the Rhesus system [RH1 (D), RHW1, RH2 (C), RH3 (E), RH4 (c), RH5 (e)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
IVR 0103	Devices intended to determine markers of the Kell system [Kel1 (K)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
IVR 0104	Devices intended to determine markers of the Kidd system [JK1 (Jka), JK2 (Jkb)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
IVR 0105	Devices intended to determine markers of the Duffy system [FY1 (Fya), FY2 (Fyb)]	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
IVR CODE	<b>Other devices intended to be used for blood grouping</b>					
IVR 0106	Other devices intended to be used for blood grouping	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

### 2. Devices intended to be used for tissue typing

IVR CODE	Devices intended to be used for tissue typing	Annexes				Conditions
		IX(I)	IX(II)	X	XI	
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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

<b>IVR 0202</b>	Other devices intended to be used for tissue typing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
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### 3. Devices intended to be used for markers of cancer and non-malignant tumours

IVR CODE	Devices intended to be used for markers of cancer and non-malignant tumours except devices for human genetic testing	Annexes				Conditions
		IX(I)	IX(II)	X	XI	
<b>IVR 0301</b>	Devices intended to be used in screening, diagnosis, staging or monitoring of cancer	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>IVR 0302</b>	Other devices intended to be used for markers of cancer and non-malignant tumours	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

### 4. Devices intended to be used for for human genetic testing

IVR CODE	Devices intended to be used for human genetic testing	Annexes				Conditions
		IX(I)	IX(II)	X	XI	
<b>IVR 0401</b>	Devices intended to be used in screening / confirmation of congenital / inherited disorders	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>IVR 0402</b>	Devices intended to be used to predict genetic disease/disorder risk and prognosis	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>IVR 0403</b>	Other devices intended to be used for human genetic testing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

### 5. Devices intended to be used to determine markers of infections / immune status

IVR CODE	Devices intended to be used for the screening, confirmation, identification of infectious agents or determination of immune status	Annexes				Conditions
		IX(I)	IX(II)	X	XI	
<b>IVR 0501</b>	Devices intended to be used for pre-natal screening of women in order to determine their immune status towards transmissible agents	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

IVR CODE	Devices intended to be used for the screening, confirmation, identification of infectious agents or determination of immune status	Annexes				Conditions
		IX(I)	IX(II)	X	XI	
IVR 0502	Devices intended to be used to detect the presence of, or exposure to transmissible agents in blood, blood components, cells, tissues or organs, or in any of their derivatives, to assess their suitability for transfusion, transplantation or cell administration	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
IVR 0503	Devices intended to be used to detect the presence of, or exposure to an infectious agent including sexually transmitted agents	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
IVR 0505	Devices intended to be used to grow / isolate / identify and handle infectious agents	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
IVR 0506	Other devices intended to be used to determine markers of infections / immune status	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

**6. Devices intended to be used for non-infectious pathologies, physiological markers, disorders / impairments (except human genetic testing), and therapeutic measures**

IVR CODE	Devices intended to be used for a specific disease	Annexes				Conditions
		IX(I)	IX(II)	X	XI	
IVR 0601	Devices intended to be used for screening / confirmation of specific disorders / impairments	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
IVR 0602	Devices intended to be used for screening, determination or monitoring of physiological markers for a specific disease	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
IVR 0603	Devices intended to be used for screening, confirmation / determination, or monitoring of allergies and intolerances	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
IVR 0604	Other devices intended to be used for a specific disease	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

<b>IVR CODE</b>	<b>Devices intended to be used to define or monitor physiological status and therapeutic measures</b>					
<b>IVR 0605</b>	Devices intended to be used for monitoring of levels of medicinal products, substances or biological components	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>IVR 0606</b>	Devices intended to be used for non-infectious disease staging	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>IVR 0607</b>	Devices intended to be used for detection of pregnancy or fertility testing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>IVR 0608</b>	Devices intended to be used for screening, determination or monitoring of physiological markers	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>IVR 0609</b>	Other devices intended to be used to define or monitor physiological status and therapeutic measures	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

### 7. Devices which are controls without a quantitative or qualitative assigned value

<b>IVR CODE</b>	<b>Controls without a quantitative or qualitative assigned value</b>	<b>Annexes</b>				<b>Conditions</b>
		<b>IX(I)</b>	<b>IX(II)</b>	<b>X</b>	<b>XI</b>	
<b>IVR 0701</b>	Devices which are controls without a quantitative assigned value	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>IVR 0702</b>	Devices which are controls without a qualitative assigned value	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

### 8. Class A devices in sterile condition

<b>IVR CODE</b>	<b>Class A devices in sterile condition</b>	<b>Annexes</b>				<b>Conditions</b>
		<b>IX(I)</b>	<b>IX(II)</b>	<b>X</b>	<b>XI</b>	
<b>IVR 0801</b>	Devices referred to in point 2.5 (rule 5), under a), of Annex VIII to Regulation (EU) 2017/746	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>IVR 0802</b>	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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

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**IVR 0803**

Specimen receptacles referred to in point 2.5 (rule 5), under c),  
of Annex VIII to Regulation (EU) 2017/746



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## II HORIZONTAL CODES

Please mark the selected horizontal areas and technologies in the grey coloured columns below. The different lists of codes are in accordance with the Implementing Regulation on the list of codes.

The areas and technologies selected will be part of the applied-for scope of application and therefore each of these areas should be linked to the conformity assessment body's competence. Conditions, such as limitations must be included when applicable (e.g. when the competence cannot be justified for the whole code).

### 1. In vitro diagnostic devices with specific characteristics

IVS CODE	In vitro diagnostic devices with specific characteristics	Select	Conditions
IVS 1001	Devices intended to be used for near-patient testing	<input type="checkbox"/>	
IVS 1002	Devices intended to be used for self-testing	<input type="checkbox"/>	
IVS 1003	Devices intended to be used as companion diagnostics	<input type="checkbox"/>	

<b>IVS 1004</b>	Devices manufactured utilising tissues or cells of human origin, or their derivatives	<input type="checkbox"/>	
<b>IVS 1005</b>	Devices in sterile condition	<input type="checkbox"/>	<p><i>Please indicate which of the following processes are covered:</i></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> aseptic processing</li> <li><input type="checkbox"/> ethylene oxide gas sterilisation (EOG)</li> <li><input type="checkbox"/> low temperature steam and formaldehyde sterilisation</li> <li><input type="checkbox"/> moist heat sterilisation</li> <li><input type="checkbox"/> radiation sterilisation (gamma, x-ray, electron beam)</li> <li><input type="checkbox"/> sterilisation with hydrogen peroxide</li> <li><input type="checkbox"/> sterilisation with liquid chemical sterilising agents</li> <li><input type="checkbox"/> thermic sterilisation with dry heat</li> <li><input type="checkbox"/> Other sterilisation processes, please specify:</li> </ul> <p><i>If designation is sought also for other processes, these need to be specified.</i></p>
<b>IVS 1006</b>	Calibrators (point 1.5 of Annex VIII to Regulation (EU) 2017/746)	<input type="checkbox"/>	
<b>IVS 1007</b>	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)	<input type="checkbox"/>	
<b>IVS 1008</b>	Instruments, equipment, systems or apparatus	<input type="checkbox"/>	
<b>IVS 1009</b>	Software that are devices in themselves including software apps, software for data analysis, and for defining or monitoring therapeutic measures	<input type="checkbox"/>	
<b>IVS 1010</b>	Devices incorporating software / utilising software / controlled by software	<input type="checkbox"/>	

## 2. In vitro diagnostic devices for which specific technologies are used

IVT CODE	In vitro diagnostic devices for which specific technologies are used	Select	Conditions
IVT 2001	In vitro diagnostic devices manufactured using metal processing	<input type="checkbox"/>	
IVT 2002	In vitro diagnostic devices manufactured using plastic processing	<input type="checkbox"/>	
IVT 2003	In vitro diagnostic devices manufactured using non-metal mineral processing (e.g. glass, ceramics)	<input type="checkbox"/>	
IVT 2004	In vitro diagnostic devices manufactured using non-metal non-mineral processing (e.g. textiles, rubber, leather, paper)	<input type="checkbox"/>	
IVT 2005	In vitro diagnostic devices manufactured using biotechnology	<input type="checkbox"/>	
IVT 2006	In vitro diagnostic devices manufactured using chemical processing	<input type="checkbox"/>	
IVT 2007	In vitro diagnostic devices which require knowledge regarding the production of pharmaceuticals	<input type="checkbox"/>	
IVT 2008	In vitro diagnostic devices manufactured in clean rooms and associated controlled environments	<input type="checkbox"/>	
IVT 2009	In vitro diagnostic devices manufactured using processing of materials of human, animal or microbial origin	<input type="checkbox"/>	
IVT 2010	In vitro diagnostic devices manufactured using electronic components including communication devices	<input type="checkbox"/>	
IVT 2011	In vitro diagnostic devices which require packaging, including labelling	<input type="checkbox"/>	

## 3. In vitro diagnostic devices which require specific knowledge in examination procedures for the purpose of product verification

IVP CODE	In vitro diagnostic devices which require specific knowledge in examination procedures	Select	Conditions
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<b>IVP CODE</b>	<b>In vitro diagnostic devices which require specific knowledge in examination procedures</b>	<b>Select</b>	<b>Conditions</b>
<b>IVP 3001</b>	In vitro diagnostic devices which require knowledge regarding agglutination tests	<input type="checkbox"/>	
<b>IVP 3002</b>	In vitro diagnostic devices which require knowledge regarding biochemistry	<input type="checkbox"/>	
<b>IVP 3003</b>	In vitro diagnostic devices which require knowledge regarding chromatography	<input type="checkbox"/>	
<b>IVP 3004</b>	In vitro diagnostic devices which require knowledge regarding chromosomal analysis	<input type="checkbox"/>	
<b>IVP 3005</b>	In vitro diagnostic devices which require knowledge regarding coagulometry	<input type="checkbox"/>	
<b>IVP 3006</b>	In vitro diagnostic devices which require knowledge regarding flow cytometry	<input type="checkbox"/>	
<b>IVP 3007</b>	In vitro diagnostic devices which require knowledge regarding immunoassays	<input type="checkbox"/>	
<b>IVP 3008</b>	In vitro diagnostic devices which require knowledge regarding lysis based testing	<input type="checkbox"/>	
<b>IVP 3009</b>	In vitro diagnostic devices which require knowledge regarding measurement of radioactivity	<input type="checkbox"/>	
<b>IVP 3010</b>	In vitro diagnostic devices which require knowledge regarding microscopy	<input type="checkbox"/>	
<b>IVP 3011</b>	In vitro diagnostic devices which require knowledge regarding molecular biological testing including nucleic acid assays and next generation sequencing (NGS)	<input type="checkbox"/>	
<b>IVP 3012</b>	In vitro diagnostic devices which require knowledge regarding physical chemistry including electrochemistry	<input type="checkbox"/>	
<b>IVP 3013</b>	In vitro diagnostic devices which require knowledge regarding spectroscopy	<input type="checkbox"/>	

<b>IVP CODE</b>	<b>In vitro diagnostic devices which require specific knowledge in examination procedures</b>	<b>Select</b>	<b>Conditions</b>
<b>IVP 3014</b>	In vitro diagnostic devices which require knowledge regarding tests of cell function	<input type="checkbox"/>	

#### 4. In vitro diagnostic devices which require specific knowledge in laboratory and clinical disciplines for the purpose of product verification

<b>IVD CODE</b>	<b>In vitro diagnostic devices which require specific knowledge in laboratory and clinical disciplines for the purpose of product verification</b>	<b>Select</b>	<b>Conditions</b>
<b>IVD 4001</b>	In vitro diagnostic devices which require knowledge regarding bacteriology	<input type="checkbox"/>	
<b>IVD 4002</b>	In vitro diagnostic devices which require knowledge regarding clinical chemistry / biochemistry	<input type="checkbox"/>	
<b>IVD 4003</b>	In vitro diagnostic devices which require knowledge regarding detection of transmissible agents (without organisms or viruses)	<input type="checkbox"/>	
<b>IVD 4004</b>	In vitro diagnostic devices which require knowledge regarding genetics	<input type="checkbox"/>	
<b>IVD 4005</b>	In vitro diagnostic devices which require knowledge regarding haematology / haemostasis, including coagulation disorders	<input type="checkbox"/>	
<b>IVD 4006</b>	In vitro diagnostic devices which require knowledge regarding histocompatibility and immunogenetics	<input type="checkbox"/>	
<b>IVD 4007</b>	In vitro diagnostic devices which require knowledge regarding immunohistochemistry / histology	<input type="checkbox"/>	
<b>IVD 4008</b>	In vitro diagnostic devices which require knowledge regarding immunology	<input type="checkbox"/>	
<b>IVD 4009</b>	In vitro diagnostic devices which require knowledge regarding molecular biology / diagnostics	<input type="checkbox"/>	
<b>IVD 4010</b>	In vitro diagnostic devices which require knowledge regarding mycology	<input type="checkbox"/>	
<b>IVD 4011</b>	In vitro diagnostic devices which require knowledge regarding parasitology	<input type="checkbox"/>	

IVD CODE	In vitro diagnostic devices which require specific knowledge in laboratory and clinical disciplines for the purpose of product verification	Select	Conditions
IVD 4012	In vitro diagnostic devices which require knowledge regarding virology	<input type="checkbox"/>	



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