# MDCG 2021- 18

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

**July 2021**

**applicable for ☐ MDR ☒ IVDR**

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

| **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[2]** | |
| **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[3]. Conformity assessment activities are identified by the corresponding reference to the Annex of the IVDR.

[1] 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.

[2] In case of a new applicant, please insert « new »

[3] 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)] | ☐ | ☐ | ☐ | ☐ | |
| **IVR 0102** | Devices intended to determine markers of the Rhesus system [RH1 (D), RHW1, RH2 (C), RH3 (E), RH4 (c), RH5 (e)] | ☐ | ☐ | ☐ | ☐ | |
| **IVR 0103** | Devices intended to determine markers of the Kell system [Kel1 (K)] | ☐ | ☐ | ☐ | ☐ | |
| **IVR 0104** | Devices intended to determine markers of the Kidd system [JK1 (Jka), JK2 (Jkb)] | ☐ | ☐ | ☐ | ☐ | |
| **IVR 0105** | Devices intended to determine markers of the Duffy system [FY1 (Fya), FY2 (Fyb)] | ☐ | ☐ | ☐ | ☐ | |
| **IVR CODE** | **Other devices intended to be used for blood grouping** | | | | | |
| **IVR 0106** | Other devices intended to be used for blood grouping | ☐ | ☐ | ☐ | ☐ | |

## 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 | ☐ | ☐ | ☐ | ☐ | |

| | | | | | | |
|---|---|---|---|---|---|---|
| **IVR 0202** | Other devices intended to be used for tissue typing | ☐ | ☐ | ☐ | ☐ | |

## 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** | |
| **IVR 0301** | Devices intended to be used in screening, diagnosis, staging or monitoring of cancer | ☐ | ☐ | ☐ | ☐ | |
| **IVR 0302** | Other devices intended to be used for markers of cancer and non-malignant tumours | ☐ | ☐ | ☐ | ☐ | |

## 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** | |
| **IVR 0401** | Devices intended to be used in screening / confirmation of congenital / inherited disorders | ☐ | ☐ | ☐ | ☐ | |
| **IVR 0402** | Devices intended to be used to predict genetic disease/disorder risk and prognosis | ☐ | ☐ | ☐ | ☐ | |
| **IVR 0403** | Other devices intended to be used for human genetic testing | ☐ | ☐ | ☐ | ☐ | |

## 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** | |
| **IVR 0501** | Devices intended to be used for pre-natal screening of women in order to determine their immune status towards transmissible agents | ☐ | ☐ | ☐ | ☐ | |

| 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 | ☐ | ☐ | ☐ | ☐ | |
| **IVR 0503** | Devices intended to be used to detect the presence of, or exposure to an infectious agent including sexually transmitted agents | ☐ | ☐ | ☐ | ☐ | |
| **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 | ☐ | ☐ | ☐ | ☐ | |
| **IVR 0505** | Devices intended to be used to grow / isolate / identify and handle infectious agents | ☐ | ☐ | ☐ | ☐ | |
| **IVR 0506** | Other devices intended to be used to determine markers of infections / immune status | ☐ | ☐ | ☐ | ☐ | |

## 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 | ☐ | ☐ | ☐ | ☐ | |
| **IVR 0602** | Devices intended to be used for screening, determination or monitoring of physiological markers for a specific disease | ☐ | ☐ | ☐ | ☐ | |
| **IVR 0603** | Devices intended to be used for screening, confirmation / determination, or monitoring of allergies and intolerances | ☐ | ☐ | ☐ | ☐ | |
| **IVR 0604** | Other devices intended to be used for a specific disease | ☐ | ☐ | ☐ | ☐ | |

| IVR CODE | 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 | ☐ | ☐ | ☐ | ☐ | |
| **IVR 0606** | Devices intended to be used for non-infectious disease staging | ☐ | ☐ | ☐ | ☐ | |
| **IVR 0607** | Devices intended to be used for detection of pregnancy or fertility testing | ☐ | ☐ | ☐ | ☐ | |
| **IVR 0608** | Devices intended to be used for screening, determination or monitoring of physiological markers | ☐ | ☐ | ☐ | ☐ | |
| **IVR 0609** | Other devices intended to be used to define or monitor physiological status and therapeutic measures | ☐ | ☐ | ☐ | ☐ | |

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

| IVR CODE | Controls without a quantitative or qualitative assigned value | Annexes | | | | Conditions |
|---|---|---|---|---|---|---|
| | | IX(I) | IX(II) | X | XI | |
| **IVR 0701** | Devices which are controls without a quantitative assigned value | ☐ | ☐ | ☐ | ☐ | |
| **IVR 0702** | Devices which are controls without a qualitative assigned value | ☐ | ☐ | ☐ | ☐ | |

## 8. Class A devices in sterile condition

| IVR CODE | Class A devices in sterile condition | Annexes | | | | Conditions |
|---|---|---|---|---|---|---|
| | | IX(I) | IX(II) | X | XI | |
| **IVR 0801** | Devices referred to in point 2.5 (rule 5), under a), of Annex VIII to Regulation (EU) 2017/746 | ☐ | ☐ | ☐ | ☐ | |
| **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 | ☐ | ☐ | ☐ | ☐ | |

| | | | | | | |
|---|---|---|---|---|---|---|
| **IVR 0803** | Specimen receptacles referred to in point 2.5 (rule 5), under c), of Annex VIII to Regulation (EU) 2017/746 | ☐ | ☐ | ☐ | ☐ | |

## 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 | ☐ | |
| **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 | *Please indicate which of the following processes are covered:* | |
| | | ☐ | aseptic processing |
| | | ☐ | ethylene oxide gas sterilisation (EOG) |
| | | ☐ | low temperature steam and formaldehyde sterilisation |
| | | ☐ | moist heat sterilisation |
| | | ☐ | radiation sterilisation (gamma, x-ray, electron beam) |
| | | ☐ | sterilisation with hydrogen peroxide |
| | | ☐ | sterilisation with liquid chemical sterilising agents |
| | | ☐ | thermic sterilisation with dry heat |
| | | ☐ | Other sterilisation processes, please specify:<br><br>*If designation is sought also for other processes, these need to be specified.* |
| **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 | ☐ | |

## 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 | ☐ | |
| **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 | ☐ | |

## 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 |
|---|---|---|---|

| IVP CODE | In vitro diagnostic devices which require specific knowledge in examination procedures | Select | Conditions |
|---|---|---|---|
| **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 | ☐ | |
| **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 CODE | In vitro diagnostic devices which require specific knowledge in examination procedures | Select | Conditions |
|---|---|---|---|
| **IVP 3014** | In vitro diagnostic devices which require knowledge regarding tests of cell function | ☐ | |

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

| IVD CODE | In vitro diagnostic devices which require specific knowledge in laboratory and clinical disciplines for the purpose of product verification | Select | Conditions |
|---|---|---|---|
| **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 | ☐ | |

| 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 | ☐ | |