applicable for ☐ MDR ☒ IVDR

NBOG F 2017-8

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.

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Review of qualification for the authorisation of personnel

This form has to be read in conjunction with the NBOG BPG 2017-2. Information has to be provided at the initial stage of selection and authorisation of personnel and every time the body review[1] the persons' qualification (i.e. when codes are added and when competence is periodically reviewed according to criteria for maintaining competence). Information given in the different sections should be supported by relevant documentation.

Initial authorisation granted on	dd/mm/yyyy	**Date and version No**
Reason for the current update	☐ periodic review of competence ☐ addition/deletion of codes ☐ modification of competence criteria ☐ others: _____	_____

1 Personal data			
Title, name			
Working languages[2]	**Understanding**	**Speaking**	**Writing**

Employment status

☐ Internal employee of the applicant (same legal entity)

☐ full-time ☐ part-time, please indicate: _____% of working time

☐ External employee on contract basis

Location of employment: _____

[1] It is expected that a review will also be performed every time the conformity assessment body competence criteria are upgraded.

[2] To be indicated in accordance with the Common European Framework of Reference for Languages, taking into account the supporting documentation provided by the person.

2 Roles [3]

☐ **Site auditor** (SA) ☐ **Lead auditor** (LA) ☐ **Project leader** (PL)

☐ **Product reviewer** (PR)**. If the product reviewer is responsible only for a specific non-code related area** (e.g. testing, biological safety), please indicate the relevant area: _____

☐ **Internal clinician** (IC) ☐ **Clinical specialist** (CS)

☐ **Final reviewer** (FR) ☐ **Decision maker** (DM)

Reference to the conformity assessment body's competence criteria used for the purpose of this authorisation (i.e. document reference and version) including criteria for maintaining competence, and process of selection and authorisation of personnel: _____

3 Relevant education

No	Date of completion and duration	Technical college / university	Relevant subject(s)	Type/level of qualification and official name of the qualification granted
3.1				
3.2				
3.3				
3.4				
Comments:				

4 Relevant working experience

No	from - to	Employer	Department / position	Responsibilities with respect to design, manufacture, testing or use of device or technologies or experience in a conformity assessment body (please indicate the codes involved in each task)[4]
4.1				
4.2				
4.3				

[3] Additional roles defined by the applicant CAB should be added to this table.

[4] In case the number of QMS audits or technical file reviews carried out are part of the competence criteria established by the notified body (e.g. minimum 40 hours CE certification audit) a reference should be provided to the specific manufacturer, role performed by the expert and relevant codes involved. When the experience has been acquired internally, the notified body should make the relevant log available upon request. When acquired externally statements / logs from the former employers should be made available.

4.4				
4.5				
4.6				
4.7				
4.8				
4.9				
Comments:				

5 Training and professional development

No	Date of completion and number of days / hours	Name of the training provider / company / organisation / university providing the training, if applicable[5]	Title of the training and appropriate description of topics covered	Certificate granted, if any
5.1				
5.2				
5.3				
5.4				
5.5				
5.6				
5.7				
5.8				
5.9				
Comments:				

6 Other relevant experience

[5] It is expected that this information will always be given except in the case of self-training.

7 Authorisation to roles / functions and codes and rationale for this authorisation including reference to information given in sections 3-6

Codes	Roles[6] acc.to sec. 2	Limitations per role[7]	Reference to sections 3 to 6	Rationale per role for the initial authorisation and/or the maintenance / limitation of the authorisation justification in case that the combination of reference in the previous column is not self-explanatory or in case of derogations from the CAB competence criteria.
IVR 0101 **Devices intended to determine markers of the ABO system** **[A (ABO1), B (ABO2), AB (ABO3)]**	**SA**			
	PR			
	IC			
	CS			
	FR			
	DM			
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 0106 **Other devices intended to be used for blood grouping**				

[6] As many lines as roles included in the scope of authorisation of the person should be included as per the example given for code IVR 0101.

[7] When a product reviewer is authorised only for a specific non –code related area, or in case the person's authorisation is limited to a specific area (e.g. clinical experts) such area should also be indicated in this column.

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**				
IVR 301 **Devices intended to be used in screening, diagnosis, staging or monitoring of cancer**				
IVR 302 **Other devices intended to be used for markers of cancer and non-malignant tumours**				
IVR 401 **Devices intended to be used in screening / confirmation of congenital / inherited disorders**				
IVR 402 **Devices intended to be used to predict genetic disease/disorder risk and prognosis**				
IVR 403 **Other devices intended to be used for human genetic testing**				
IVR 501 **Devices intended to be used for pre-natal screening of women in order to determine their immune status towards transmissible agents**				
IVR 502 **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 503 **Devices intended to be used to detect the presence of, or exposure to an infectious agent including sexually transmitted agents**				
IVR 504 **Devices intended to be used to detect the presence of, or exposure to an infectious agent including sexually transmitted agents**				
IVR 505 **Devices intended to be used to grow / isolate / identify and handle infectious agents**				
IVR 506 **Other devices intended to be used to determine markers of infections / immune status**				
IVR 601 **Devices intended to be used for screening / confirmation of specific disorders / impairments**				
IVR 602 **Devices intended to be used for screening, determination or monitoring of physiological markers for a specific disease**				
IVR 603 **Devices intended to be used for screening, confirmation / determination, or monitoring of allergies and intolerances**				
IVR 604 **Other devices intended to be used for a specific disease**				
IVR 605 **Devices intended to be used for monitoring of levels of medicinal products, substances or biological components**				
IVR 606 **Devices intended to be used for non-infectious disease staging**				
IVR 607 **Devices intended to be used for detection of pregnancy or fertility testing**				

IVR 608 **Devices intended to be used for screening, determination or monitoring of physiological markers**				
IVR 609 **Other devices intended to be used to define or monitor physiological status and therapeutic measures**				
IVR 701 **Devices which are controls without a quantitative assigned value**				
IVR 702 **Devices which are controls without a qualitative assigned value**				
IVR 801 **Devices referred to in point 2.5 (rule 5), under a), of Annex VIII to Regulation (EU) 2017/746**				
IVR 802 **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 803 **Specimen receptacles referred to in point 2.5 (rule 5), under c), of Annex VIII to Regulation (EU) 2017/746**				
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**				

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**				
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**				
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 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**				
IVD 4012 **In vitro diagnostic devices which require knowledge regarding virology**				

For completeness and correctness

_____
date

_____
Personnel signature

For granting of authorisation

_____
date

_____
Personnel responsible for autorisation signature