MDCG 2021-16

Application form to be submitted by a conformity assessment body when applying for designation as notified body under Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices (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

applicable for ☐ MDR ☒ IVDR

Application form to be submitted by a conformity assessment body when applying for designation as notified body under the *in vitro* diagnostic devices Regulation (IVDR)[1]

This form describes the information to be submitted by notified bodies when applying for designation under the MDR. Numbers in brackets refer to the relevant sections of Annex VII to Regulation (EU) 2017/746.

All of the supporting documents that will be provided for each of the numbered sections should be listed in a separate line indicating the identification number, the title and the date or revision of the document. When only a section or page of a document is relevant for the specific requirement, reference should be done to such section and/or page. If a requirement listed in a numbered section is considered as not applicable, applicant conformity assessment bodies should write "NA" in the line below. If possible, applicant conformity assessment bodies should use hyperlinks and a file structure.

The grey coloured column on the right side should be used only by designating authorities for recording their completeness check (as per Art. 39 to the MDR). If the tick box shows "X" or (manually) "✓" the designating authority confirms that the supporting documentation have been provided for the specific requirement. In case any tick box stays empty but the application is considered complete, a brief justification should be included in the box provided in the last page.

BASIC INFORMATION
Name of the national authority responsible for notified bodies (DA)
Name of the applicant conformity assessment body (CAB)
If applicable, notified body's identification number[2]
Address of the CAB
Contact person

[1] This document was endorsed by MDCG and published as NBOG F 2017-2 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 new applicants, please insert « new »

E-mail

Telephone

Company registration number and company register

Date of application

No	Information requested Supporting documentation provided	FOR DA USE

1. ORGANISATIONAL AND GENERAL REQUIREMENTS

General documentation

1.1	Scope of designation requested under the IVDR (NBOG F 2017-4 / MDCG 2021-18 Notification form to be appended)	☐

1.2	Authorisation to represent the conformity assessment body by the person who has submitted the application on behalf of the body, unless such authorisation follows from the documentation specified in point 1.5.	☐

1.3	Valid accreditation certificate and the corresponding evaluation report as referred to in Article 34 (2) of Regulation (EU) 2017/746	☐

1.4	Compliance strategy explaining how the requirements set out in Annex VII of Regulation (EU) 2017/746 have been fulfilled, including, in the case of notified bodies designated under Directive of the European Parliament and the Council 98/79/EC, a gap analysis explaining how the alignment to the new requirements of the Regulations has been achieved	☐

Legal status and organisational structure

1.5	Documentation detailing the conformity assessment body's legal personality and its status, including information about ownership and the legal or natural persons exercising control over the conformity assessment body (1.1.1)	☐

1.6	Documentation detailing the activities of the organisation to which the conformity assessment body belongs, the organisational structure and governance of that organisation, and its relationship with the conformity assessment body (1.1.2)	☐

1.7	Documentation detailing the activities and responsibilities of any legal entity which is wholly or partly owned by the conformity assessment body or which wholly or partly	☐

No	Information requested Supporting documentation provided	FOR DA USE
	owns the conformity assessment body, and the legal and operational relationships with the conformity assessment body (1.1.3)	
1.8	Documentation describing the organisational structure, the allocation of responsibilities, reporting lines and the operational management of the conformity assessment body (1.1.4)	☐
1.9	Documentation detailing the functions, responsibilities and authorities of the top-level management, including the individual having overall responsibility for all conformity assessment activities in relation to devices (head of the notified body) (1.1.5, 1.1.6 and 3.1.1)	☐
	Independence, impartiality and confidentiality	
1.10	Documentation detailing the structures, policies and procedures the conformity assessment body has in place to safeguard and promote the principles of independence, impartiality and objectivity throughout its organisation, personnel and activities, including procedures providing for the identification, investigation and resolution of any case in which a conflict of interest may arise (1.2.1, 1.2.2, 1.2.3, 1.2.7, 2.4, 4.5.1 and 4.5.3)	☐
1.11	Documentation detailing how the conformity assessment body ensures that the activities of its owners, its subsidiaries and subcontractors (including external experts), or of any associated body do not affect its independence and impartiality or the objectivity of its conformity assessment activities (1.2.7, 2.4 and 3.4.2)	☐
1.12	If the conformity assessment body is owned by a public entity or institution, documentation detailing how independence and absence of any conflict of interest with the authority responsible for notified bodies and/or the competent authority is ensured (1.2.6)	☐
1.13	Documentation detailing involvement of personnel in consultancy services in the field of devices prior to taking up employment with the conformity assessment body and detailing monitoring and resolution of potential conflicts of interest (1.2.4)	☐

No	Information requested Supporting documentation provided	FOR DA USE

1.14	Documentation detailing the conditions governing the remuneration of all employees (including top-level management and contracted staff) (1.2.5)	☐

1.15	Documentation detailing how the conformity assessment body ensures that its personnel, committees, subsidiaries, subcontractors, and any associated body or personnel of external bodies respect the confidentiality of the information (including proprietary rights) which comes into their possession when carrying out their tasks (1.3.1, 1.3.2 and 2.4) and documentation on professional secrecy arrangements (3.4.2)	☐

Liability insurance and financial resources

1.16	Documentation on the liability insurance covering conformity assessment activities, including its scope and overall financial value (1.4)	☐

1.17	Documentation detailing the conformity assessment body's financial resources, including its financial capacity and long-term economic viability (1.5)	☐

2. QUALITY MANAGEMENT REQUIREMENTS

#	Documentation on the quality management system addressing at least the following:	
2.1	– management system structure and the list of all quality management system documents, and the sequence and interrelation of processes (2.2)	☐

2.2	– the quality manual and policies and objectives for the conformity assessment body's activities (2.2)	☐

2.3	– control of documents including verification that the documents have the same content where documents are used in different languages (2.2)	☐

No	Information requested Supporting documentation provided	FOR DA USE
2.4	– control of records (2.2)	☐
2.5	– management reviews (2.2)	☐
2.6	– internal audits (2.2) and monitoring of the conformity assessment activities and performance of personnel and subcontractors (3.5.1)	☐
2.7	– corrective and preventive actions (2.2)	☐
2.8	– complaints and appeals (2.2)	☐
2.9	Documentation relating to the implementation and maintenance of the quality management system throughout the conformity assessment body's organisation, including subsidiaries and subcontractors involved in conformity assessment activities (2.3)	☐
2.10	Model declaration of commitment of the conformity assessment body's personnel to comply with the procedures defined by the body (2.4)	☐

3. RESOURCE REQUIREMENTS

General documentation

3.1	Matrix based on the established (specific) qualification criteria in accordance with section 3.4 of this document, detailing the authorisations (including any limitations) and	☐

No	Information requested Supporting documentation provided	FOR DA USE
	responsibilities in respect of conformity assessment activities, and functions, fields of competence, employment status (e.g. full-time, external, etc.) and location of all internal and external personnel referred to in Sections 3.2.3-3.2.7 of Annex VII of Regulation (EU) 2017/746; the authorisations and responsibilities in respect of conformity assessment activities shall be specified by using the codes set out in the Commission Implementing Regulation (EU) 2017/2185 on codes and corresponding types of devices, see NBOG F-2017-4 / MDCG 2021-18 (3.3.2)	
3.2	List of any additional personnel (other than referred to in 3.1) supporting conformity assessment activities, detailing the duties, responsibilities and level of authorisation (job descriptions), employment status (e.g. full-time, external, etc.) and location of each individual (3.1.1, 3.1.3 and 3.4.1)	☐
3.3	Templates of employment and other contracts used for the conformity assessment body's personnel	☒
3.4	Documentation detailing the established (specific) qualification criteria for each function within the conformity assessment process, as well as the types of devices, technologies and areas within the subdivisions of the scope of designation applied for (3.2). The qualification criteria shall be specified at least for each of the following roles and function categories:	
	– personnel responsible for establishing qualification criteria and authorising personnel to conformity assessment activities (3.2.3)	☐
	– personnel with relevant clinical expertise (3.2.4)	☐
	– product reviewer (3.2.5)	☐
	– site auditor (3.2.6)	☐
	– personnel with overall responsibility for final reviews and decision-making on certification (3.2.7)	☐
3.5	Documentation relating to the procedures for the selection and authorisation of persons involved in conformity assessment activities, including the procedures to document the qualification of each person and the satisfaction of the qualification criteria (3.2.1 and 3.3.1)	☐
3.6	Representative sample of records (at least one per function) demonstrating compliance with the qualification criteria for the authorisation of the personnel member (3.3.2)	☐

No	Information requested Supporting documentation provided	FOR DA USE

Monitoring, training, exchange of experience

3.7	Documentation detailing the initial evaluation, on-going monitoring and periodic review of competence of the internal and external personnel, including the identification of training needs and drawing up of training plans (3.5.1 and 3.5.2)	☐
3.8	Documentation detailing a continuous training and education programme (2.2 and 3.1.2)	☐
3.9	Documentation detailing the implementation of a system for exchange of experience (3.1.2)	☐
3.10	Documentation detailing how the personnel is informed of any relevant standardisation activities, legislation, guidance, and the activities of the notified body coordination group referred to in Article 45 of Regulation (EU) 2017/746 (1.6.1 and 3.5.2)	☐

Equipment and facilities

3.11	List of all tests that the conformity assessment body will be able to perform and of the relevant equipment and facilities, including testing facilities, in possession of the conformity assessment body and which are to be used in its conformity assessment activities (3.1.1)	☐

Subcontractors

3.12	Lists of all subcontractors and subsidiaries as referred to in Article 33 of Regulation (EU) 2017/746, including a description of their functions in relation to conformity assessment activities (e.g. external laboratories) or administrative tasks (e.g. information technologies) and contractual arrangements in place (3.1.1 and 3.4.1)	☐

No	Information requested Supporting documentation provided	FOR DA USE

3.13	Documentation detailing the procedures for selecting, evaluating and monitoring the competence of subcontractors involved in conformity assessment activities (3.5.1)	☐

3.14	Documentation detailing the conditions under which subcontracting may take place (3.4.2)	☐

3.15	Documentation demonstrating internal competence in each product area for the conformity assessment activities for which subcontractors or external experts are used (3.4.3)	☐

4. PROCESS REQUIREMENTS

Quotations, pre-application activities, application review and contract

#	Documentation relating to procedures for quotations and pre-application activities, including:	
4.1	− description of the application procedure by which manufacturers can obtain certification (4.2(a))	☐

4.2	− fees charged and financial conditions (4.2(b))	☐

4.3	− advertising of conformity assessment services (4.2(c))	☐

4.4	− review of pre-application information (4.2(d))	☐

#	Documentation relating to contractual arrangements between the manufacturer and the conformity assessment body, including	
4.5	− template application form (4.3)	☐

No	Information requested Supporting documentation provided	FOR DA USE

4.6	– template contract specifying terms and conditions and obligations of the conformity assessment body in relation to conformity assessment activities (4.3)	☐

4.7	Procedures relating to review of applications(4.3):	
	– the verification of completeness of the application	☐
	– the verification of the qualification and classification of the product	☐
	– the applicability of the conformity assessment procedures chosen by the applicant	☐
	– the ability of the conformity assessment body to assess the application in accordance with the scope of designation applied for	☐
	– the availability of sufficient and appropriate resources	☐

4.8	Procedures to ensure that all contracts relating to the conformity assessment activities are concluded directly between the manufacturer and the conformity assessment body (4.2(e))	☐

Allocation of resources

4.9	Procedures and forms to ensure that conformity assessment activities are conducted by appropriately qualified and authorised personnel, including the identification of one individual responsible for each application, and that allocation of tasks and changes thereto are documented (4.4 and 4.5.1)	☐

#	Documentation relating to project planning (4.5.1), including	
4.10	– planning the conduct of each individual project and specifying the rationale for fixing time limits for completion of the conformity assessment	☐

4.11	– rotation of the members of the assessment team at appropriate intervals	☐

No	Information requested	FOR DA USE
	Supporting documentation provided	

Conformity assessment activities

4.12	Documentation relating to the assessment of manufacturers' technical documentation (4.5.1 and 4.5.3), including:	☐
4.13	– intentionally empty to ensure consistent numbering with the MDR application	☐
4.14	– the review of the manufacturer's procedures and documentation relating to performance evaluation of *in vitro* diagnostic medical devices (4.5.1 and 4.5.5)	☐
4.15	– the assessment of the interface between the manufacturer's risk management process and its appraisal and analysis of the performance evaluation (4.5.1)	☐
4.16	– assessments of technical documentations for class B and class C in vitro diagnostic medical devices selected on a representative basis and according to a sampling plan (4.5.1, 4.5.2(a) and 4.10)	☐
4.17	– validation of the summary of safety and performance in accordance with Article 29 of Regulation (EU) 2017/746	☐
4.18	Documentation relating to quality management system audits according to each specific conformity assessment activity covered by the application and the class of the device (4.5.2)	☐
4.19	Documentation relating to type-examination, including establishment of test plans (4.5.3)	☐

No	Information requested Supporting documentation provided	FOR DA USE
4.20	Documentation relating to verification by examination and testing of every product batch, including establishment of test plans (4.5.3)	☐
4.21	Documentation relating to carrying out the specific procedures referred to in Sections 5 of Annex IX to Regulation (EU) 2017/746 (4.5.1 and 4.5.5)	☐

Final review and decision making on certification

4.22	Documentation relating to the final review process carried out prior to making a final decision (4.7)	☐
4.23	Documentation relating to the final decision process prior to the issuance, suspension, restriction or withdrawal of a certificate and the communication to the manufacturer (4.8)	☐
4.24	Certificate templates intended to be used for the different types of conformity assessments for which the conformity assessment body seeks designation, in accordance with Annex XII of Regulation (EU) 2017/746 (4.8)	☐

Post-certification activities

4.25	Documentation detailing the information obligations and communications with the electronic system referred to in Article 52 of Regulation (EU) 2017/746 (4.8)	☐
4.26	Documentation relating to the review of periodic safety update reports referred to in Article 81 of Regulation (EU) 2017/746	☐
4.27	Documentation relating to surveillance and post-certification monitoring (4.10), including	☐

No	Information requested Supporting documentation provided	FOR DA USE
4.28	– screening of relevant sources of scientific and clinical data and post-market information relating to the scope of designation	☐
4.29	– review, documentation and management of vigilance information	☐
4.30	– estimation of the impact of vigilance information on the validity of existing certificates	☐
4.31	– taking any appropriate actions	☐
4.32	– surveillance audits (4.5 and 4.10)	☐
4.33	– unannounced audits (4.5 and 4.10)	☐
4.34	Documentation relating to sampling of devices (4.5.1 and 4.10)	☐
4.35	Documentation detailing manufacturers' information obligations and the conformity assessment body's assessment of changes (4.9)	☐
4.36	Documentation detailing the conduct of re-certification reviews and the renewal of certificates (4.11)	☐

No	Information requested	FOR DA USE
	Supporting documentation provided	

4.37	Documentation relating to voluntary changes of a notified body in accordance with Article 53 of Regulation (EU) 2017/746	☐

5. MOCK-UP FILES

5.1	Only to be provided at the beginning of the on-site assessment If applicable, please indicate how many mock up (including technical documentation and the assessment thereof) will be made available at the beginning of the onsite assessment, including the type of devices and the conformity assessment activities to be covered.	☐

In case any tick box above stays empty, please provide a brief justification for considering the application complete