MDCG 2024-8 revision 1 changes
Update the document to remove section G.4 due to redundancy in its use by notified bodies

MDCG 2024-8 Rev. 1

Preliminary assessment review template – IVDR (Regulation (EU) 2017/746)

Revision 1 – January 2025

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.

Preliminary assessment review template[1]- IVDR (Regulation (EU) 2017/746)

DETAILS ON THE APPLICATION AND THE REVIEWERS		
Name and (if applicable) identification number of Conformity Assessment Body (CAB)		
Name of Designating Authority (DA)		
DA's reference number(s)		
Purpose of the application	☐ Initial Designation	
	☐ Extension of the scope of designation	Codes and/or conformity assessment activities (if applicable) to be added[2]:
Date the application was received by DA[3]		
Languages in which the application and supporting documents were provided		
Date on which the application has been sent to the European Commission together with the completeness check form		
Name of the reviewer(s)[4]		
Date(s) of the review		

[1] This form will be used to document the review of the CAB´s application by the DA. This document might be used as a living document during different steps of the review once the completeness check has been concluded. Nevertheless, only the final version of this report should be sent to the European Commission either after all deficiencies which are obstacles for an onsite assessment have been clarified or in case the DA has made the final decision that an on-site assessment should not be conducted. The European Commission will only start the process of appointment of the Joint Assessment Team according to Article 35 (3) to the IVDR after a final decision has been taken and documented by the DA in section "Outcome of the review" of the final version of the report. For details see MDCG 2022-13 Designation, re-assessment and notification of conformity assessment bodies and notified bodies.

[2] In case of extension of the scope of designation, the completion of this form will be limited to the specific sections and information relevant to the extension of the scope of designation. For example, section 3 (Resources) should describe the changes to the matrix and personnel which support the addition of codes. For details see in MDCG 2022-13 section on Assessments relating to extension of the scope of the designation.

[3] Supporting documents, including new or updated documents after the original application, may be listed in the Annex (List of Documents) and attached to this PAR form.

[4] In case of use by more than one reviewer entries should be traceable, e.g. by prefacing each comment/section with the initials of the reviewer or by using different colors.

In case the form is used by the DA for intermediate stages of the review, date(s) of previous review(s)/report(s) on this application	

OUTCOME OF THE REVIEW[5]		
On the basis of the documents received should it be envisaged to conduct an onsite assessment?	☐ Yes ☐ Yes, with issues described below to be clarified during the on-site assessment	Indicate proposed on-site assessment dates:
	☐ No, the deficiencies described below have to be clarified before an onsite assessment can be envisaged[6]	
DA's general comments on the application, if applicable		

[5] This section is to be filled in at the end of the review, once all of the documentation has been examined.

[6] This report is only to be sent to the European Commission after all deficiencies which are obstacles for an onsite assessment have been clarified by the DA (or in case the DA has made the final decision that an onsite assessment should not be conducted).

REVIEW OF THE APPLICATION

G. GENERAL DOCUMENTATION		
List of comments on single documents[7]		
G.1 Scope of designation requested under the IVDR		
MDCG 2021-18	*Comment*	
Title and Revision Document 2	*Comment*	
G.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 1.1.1		
Title and Revision Document 1	*Comment*	
Title and Revision Document 2	*Comment*	
G.3 Valid accreditation certificate and the corresponding evaluation report as referred to in Article 34(2) of Regulation (EU) 2017/746		
Title and Revision Document 1	*Comment*	
Title and Revision Document 2	*Comment*	
1. ORGANISATIONAL AND GENERAL REQUIREMENTS		
List of comments on single documents[7]		
1.1 Legal status and organisational structure		
1.1.1 Annex VII	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	MDCG 2019-6[8] Q I.2
Title and Revision Document 1	*Comment*	
Title and Revision Document 2	*Comment*	
1.1.2 Annex VII	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	MDCG 2019-6 Q I.3 Q I.4
Title and Revision Document 1	*Comment*	
Title and Revision Document 2	*Comment*	
1.1.3 Annex VII	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 owns the conformity assessment body, and the legal and operational relationships with the conformity assessment body	
Title and Revision Document 1	*Comment*	
Title and Revision Document 2	*Comment*	

[7] Please restrict the text to issues to be clarified. A summary of the content of the documents or the fulfillment of criteria is not requested. Only (potential) nonconformities and questions to be clarified should be described. This needs to be detailed as much as possible. For each item, the respective section / paragraph of the documents should be indicated.

[8] The third column refers to legal provisions (in IVDR or other Union legislation) and MDCG guidance also applicable to the specific requirement in IVDR Annex VII.

1.1.4 - 1.1.5 Annex VII	Documentation describing the organisational structure, the allocation of responsibilities, reporting lines and the operational management conformity assessment body	MDCG 2019-6 Q I.4
Title and Revision Document 1	*Comment*	
Title and Revision Document 2	*Comment*	
1.1.6 Annex VII	Documentation detailing the functions, responsibilities and authorities of the top-level management, indicating the overall authority and responsible person for each of the following:	
Provision of adequate resources for conformity assessment activities	*Responsible person (position or role, no individual name)* *Relevant documents and Comment*	
Development of procedures and policies for the operation of the notified body	*Responsible person (position or role, no individual name)* *Relevant documents and Comment*	
Supervision of implementation of the procedures, policies and quality management systems of the notified body	*Responsible person (position or role, no individual name)* *Relevant documents and Comment*	
Supervision of the notified body's finances	*Responsible person (position or role, no individual name)* *Relevant documents and Comment*	
Activities and decisions taken by the notified body, including contractual agreements	*Responsible person (position or role, no individual name)* *Relevant documents and Comment*	
Delegation of authority to personnel and/or committees, where necessary, for the performance of defined activities	*Responsible person (position or role, no individual name)* *Relevant documents and Comment*	
Interaction with the authority responsible for notified bodies and the obligations regarding communications with other competent authorities, the Commission and other notified bodies	*Responsible person (position or role, no individual name)* *Relevant documents and Comment*	
Individual having overall responsibility for all conformity assessment activities in relation to devices (head of the notified body)	*Responsible person (position or role, no individual name)* *Relevant documents and Comment*	Annex VII 3.1.1 Last paragraph
1.2 Independence and impartiality		
1.2.1 - 1.2.2 Annex VII	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 whole organisation (e.g. corporate group), personnel and activities, including procedures providing for the identification, investigation and resolution of any case in which a conflict of interest may arise	Annex VII 1.1.2 MDCG 2019-6 Q I.3 Q I.4 Q I.5 Q I.9
Personnel commitment and written statement	*Comment*	Annex VII 2.4
Title and Revision Document 2	*Comment*	

1.2.3 - 1.2.7 Annex VII	<u>Independence of the notified body, the larger organisation to which it belongs, the top-level management and conformity assessment personnel</u> Documentation on ensuring independence and impartiality with respect to: - IVD Medical device industry (1.2.3) - Consultancy activities (1.2.3 - 1.2.4) - Remuneration (1.2.5) - Declarations of interest by top-level management (1.2.5) - Public ownership (1.2.6) - Subsidiaries, subcontractors and external experts (1.2.7; 3.4.2)	Article 49.5 Annex VII 1.1.2 1.2.9 2.4 MDCG 2019-6 Q I.3 Q I.4 Q I.5 Q I.6 Q I.8 Q I.9
Title and Revision Document 1	*Comment*	
Title and Revision Document 2	*Comment*	
1.2.8 Annex VII	Documentation demonstrating how the conformity assessment body operates with a set of consistent, fair and reasonable terms and conditions, taking into account small and medium size businesses	
Title and Revision Document 1	*Comment*	
Title and Revision Document 2	*Comment*	
1.3 Confidentiality		
1.3.1 - 1.3.2 Annex VII	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 and secrecy of the information (including proprietary rights) which comes into their possession	
Personnel commitment and written statement	*Comment*	Annex VII 2.4; 3.4.2
Title and Revision Document 2	*Comment*	
1.4 Liability		
1.4.1 - 1.4.2 Annex VII	Documentation on the liability insurance covering conformity assessment activities, including its scope and overall financial value	MDCG 2019-6 Q I.10
Title and Revision Document 1	*Comment*	
Title and Revision Document 2	*Comment*	
1.5 Financial requirements		
1.5 Annex VII	Documentation detailing the conformity assessment body's financial resources, including its financial capacity and long-term economic viability	
Title and Revision Document 1	*Comment*	
Title and Revision Document 2	*Comment*	

1.6 Participation in coordination activities		
1.6.1 - 1.6.2 Annex VII	Documentation on the CAB's procedures ensuring its personnel is involved in standardisation activities and in the work of the notified body coordination group and how personnel are informed. Strategy to take into consideration guidance and best practice documents	Article 45 MDCG 2019-6 Q I.1
Title and Revision Document 1	*Comment*	
Title and Revision Document 2	*Comment*	

2. QUALITY MANAGEMENT REQUIREMENTS		
List of comments on single documents[9]		
2.1 - 2.2 first indent Annex VII	Management system structure and the list of all quality management system documents, including policies and objectives	Annex VII 4.1
Title and Revision Document 1	*Comment*	
Title and Revision Document 2	*Comment*	
2.2 second indent Annex VII	Policies for assignment of activities and responsibilities to personnel	
Title and Revision Document 1	*Comment*	
Title and Revision Document 2	*Comment*	
2.2 third indent Annex VII	Documentation detailing the assessment and decision-making processes in accordance with the tasks, responsibilities and role of the notified body's personnel and top-level management	
Title and Revision Document 1	*Comment*	
Title and Revision Document 2	*Comment*	
2.2 fourth indent Annex VII	Documentation detailing the planning, conduct, evaluation and, if necessary, adaptation of the conformity assessment procedures	
Title and Revision Document 1	*Comment*	
Title and Revision Document 2	*Comment*	
2.2 fifth indent Annex VII	Procedures for control of documents including verification that the documents have the same content where documents are used in different languages	Annex VII 2.2 Last paragraph
Title and Revision Document 1	*Comment*	
Title and Revision Document 2	*Comment*	
2.2 sixth indent Annex VII	Procedures for control of records	
Title and Revision Document 1	*Comment*	
Title and Revision Document 2	*Comment*	
2.2 seventh indent Annex VII	Procedures for management review	
Title and Revision Document 1	*Comment*	
Title and Revision Document 2	*Comment*	

[9] Please restrict the text to issues to be clarified. A summary of the content of the documents or the fulfillment of criteria is not requested. Only (potential) nonconformities and questions to be clarified should be described. This needs to be detailed as much as possible. For each item, the respective section / paragraph of the documents should be indicated.

2.2 eighth indent Annex VII	Procedures for internal audits	
Title and Revision Document 1	*Comment*	
Title and Revision Document 2	*Comment*	
2.2 ninth indent Annex VII	Procedures for corrective and preventive actions	
Title and Revision Document 1	*Comment*	
Title and Revision Document 2	*Comment*	
2.2 tenth indent Annex VII	Procedures for complaints and appeals	
Title and Revision Document 1	*Comment*	
Title and Revision Document 2	*Comment*	
2.2 eleventh indent Annex VII	Procedures for continuous training	Annex VII 3.1.2 3.5.2
Title and Revision Document 1	*Comment*	
Title and Revision Document 2	*Comment*	
2.3 Annex VII	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	
Title and Revision Document 1	*Comment*	
Title and Revision Document 2	*Comment*	
2.4 Annex VII	Model declaration of commitment of the CAB's personnel to comply with the procedures	
Title and Revision Document 1	*Comment*	
Title and Revision Document 2	*Comment*	
Articles 32.2 40.2 40.3	Procedures on the NB's obligation to make available and submit upon requests all relevant documentation	
Title and Revision Document 1	*Comment*	
Title and Revision Document 2	*Comment*	
Articles 40.1 42.3 42.5 42.9	Procedures on the NB's obligation for information of relevant changes and ceasing of activities	
Title and Revision Document 1	*Comment*	
Title and Revision Document 2	*Comment*	

3. RESOURCE REQUIREMENTS		
List of comments on single documents[10]		
3.1 General		
3.1.1 Annex VII	<u>Documentation detailing the CAB's:</u> - Equipment, facilities and competence (including testing facilities) needed to perform properly the technical, scientific and administrative tasks - Permanent availability of personnel and in sufficient numbers, including templates of employment and other contracts used for the personnel - Sufficient internal competence to critically evaluate assessments conducted by external expertise (3.4.3)	Article 32.1 MDCG 2019-6 Q III.2 Q III.3
Title and Revision Document 1	*Comment*	
Title and Revision Document 2	*Comment*	
3.1.2 Annex VII	Documentation detailing the implementation of a system for exchange of experience and a continuous training and education programme	
Title and Revision Document 1	*Comment*	
Title and Revision Document 2	*Comment*	
3.1.3 Annex VII	<u>Documentation detailing:</u> - The extent and limits of duties and responsibilities of the personnel, including subcontractors and external experts - The level of authorisation of the personnel - The process for information the personnel accordingly	
Title and Revision Document 1	*Comment*	
Title and Revision Document 2	*Comment*	
3.2 Qualification criteria in relation to personnel		
3.2.1 - 3.2.2 Annex VII	<u>Documentation detailing:</u> - Process to establish and document the qualification criteria (providing a sufficient level of detail for the required qualification within the subdivisions of the applied-for scope) - Process for selection and authorisation of personnel, including the required initial and ongoing training	NBOG BPG 2017-2
Title and Revision Document 1	*Comment*	
Title and Revision Document 2	*Comment*	

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3.2.2 - 3.2.7 Annex VII	- Specific qualification criteria (3.2.2) Qualification criteria per role: - Personnel responsible for establishing qualification criteria and for authorising other personnel (3.2.3) - Personnel with relevant clinical expertise (Internal clinician/Clinical specialist) (3.2.4) - Product reviewers (3.2.5) - Site auditors (3.2.6) - Final reviewers and decision-makers (3.2.7)	Article 32.1 (employed by) NBOG BPG 2017-2 MDCG 2019-6 Q III.4 Q III.6 Q III.7 Q IV.6
Title and Revision Document 1	*Comment*	
Title and Revision Document 2	*Comment*	
3.3 Documentation of qualification, training and authorisation of personnel		
3.3.1 Annex VII	Procedure in place to fully document the qualification of each member of personnel and the satisfaction of the qualification criteria	NBOG BPG 2017-2 MDCG 2019-6 Q III.1
Title and Revision Document 1	*Comment*	
Title and Revision Document 2	*Comment*	
3.3.2 first indent Annex VII	Matrix detailing the authorisations (including any limitations) and responsibilities of the personnel, including employment status (e.g. full-time, external, etc.) and location of all internal and external personnel; the authorisations shall be specified by using the codes set out in the Commission Implementing Regulation on codes and corresponding types of devices	MDCG 2021-14
Title and Revision Document 1	*Comment*	
Title and Revision Document 2	*Comment*	
3.3.2 second indent Annex VII	Model/template of the record attesting authorisation of qualified personnel; the records shall contain a rationale for defining the scope of the responsibilities for each of the assessment personnel and records of the conformity assessment activities carried out by each of them Representative sample of records (at least one per role/function) demonstrating compliance with the qualification criteria for the authorisation of the personnel member (mock file or blacked out document might be acceptable)	
Title and Revision Document 1	*Comment*	
Title and Revision Document 2	*Comment*	
3.4 Subcontractors and external experts		
3.4.1 Annex VII	Lists of all subcontractors and subsidiaries, 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	Article 33 Article 52(a)
Title and Revision Document 1	*Comment*	
Title and Revision Document 2	*Comment*	

3.4.2 Annex VII	Documentation detailing the conditions under which subcontracting may take place	
Title and Revision Document 1	*Comment*	
Title and Revision Document 2	*Comment*	
3.5 Monitoring of competences, training, exchange of experience		
3.5.1 - 3.5.2 Annex VII	<u>Documentation detailing:</u> -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 - How the personnel is aware of Union and national law in force on devices, relevant harmonised standards, CS, guidance documents and the results of the coordination activities of NBCG-Med - Verification that personnel takes part in the internal exchange of experience and the continuous training and education programme	Article 45 MDCG 2019-6 Q III.5
Title and Revision Document 1	*Comment*	
Title and Revision Document 2	*Comment*	

4. PROCESS REQUIREMENTS		
List of comments on single documents[11]		
4.1 General		
4.1 1st paragraph Annex VII	Overview of processes for the conduct of each conformity assessment activity comprising the individual steps from pre-application activities up to decision-making and surveillance, e.g. flowcharts	Annex VII 2.1
Title and Revision Document 1	*Comment*	
Title and Revision Document 2	*Comment*	
4.1 2nd paragraph Annex VII	Documentation detailing the internal activities of the CAB which shall not be subcontracted	MDCG 2019-6 Q III.6
Title and Revision Document 1	*Comment*	
Title and Revision Document 2	*Comment*	
4.2 Notified body quotations and pre-application activities		
4.2 (a) Annex VII	Description of the application procedure by which manufacturers can obtain certification, including which languages are acceptable	MDCG 2019-6 Q I.6
Title and Revision Document 1	*Comment*	
Title and Revision Document 2	*Comment*	
4.2 (b) Annex VII	Procedures relating to fees charged and financial conditions	Article 46 MDCG 2019-6 Q V.2 MDCG 2023-2
Title and Revision Document 1	*Comment*	
Title and Revision Document 2	*Comment*	
4.2 (c) Annex VII	Procedures in relation to advertising of conformity assessment services	
Title and Revision Document 1	*Comment*	
Title and Revision Document 2	*Comment*	
4.2 (d) Annex VII	Procedures relating to the review of pre-application information	Manual on borderline and classification MDCG 2020-16
Title and Revision Document 1	*Comment*	
Title and Revision Document 2	*Comment*	

[11] Please restrict the text to issues to be clarified. A summary of the content of the documents or the fulfillment of criteria is not requested. Only (potential) nonconformities and questions to be clarified should be described. This needs to be detailed as much as possible. For each item, the respective section / paragraph of the documents should be indicated.

4.2 (e) Annex VII	Procedures to ensure that all contracts relating to the conformity assessment activities are concluded directly between the manufacturer and the conformity assessment body	
Title and Revision Document 1	*Comment*	
Title and Revision Document 2	*Comment*	
4.3 Application review and contract		
4.3 1st paragraph Annex VII	Template application form	MDCG 2019-6 Q I.7
Title and Revision Document 1	*Comment*	
Title and Revision Document 2	*Comment*	
4.3 2nd paragraph Annex VII	Template contract including terms and conditions and obligations of the CAB in relation to conformity assessment activities (terms and conditions might be in a separate annex to the contract template)	
Title and Revision Document 1	*Comment*	
Title and Revision Document 2	*Comment*	
4.3 (a) – (e) Annex VII	Procedures relating to review of applications, including documented outcome of each review and notification to EUDAMED of refusals or withdrawals of applications	Article 49.2 Application sections in Annex IX-XI
Title and Revision Document 1	*Comment*	
Title and Revision Document 2	*Comment*	
4.4 Allocation of resources		
4.4 1st and 2nd paragraph Annex VII	Procedures and forms to ensure that conformity assessment activities are conducted by appropriately qualified and authorised personnel, and that allocation of tasks and changes thereto are documented	Annex VII 4.5.1 second indent MDCG 2019-6 Q IV.6 Q IV.7 MDCG 2021-14
Title and Revision Document 1	*Comment*	
Title and Revision Document 2	*Comment*	
4.4 2nd paragraph Annex VII	Procedures and forms to identify one individual responsible for each application	MDCG 2019-6 Q IV.7
Title and Revision Document 1	*Comment*	
Title and Revision Document 2	*Comment*	

4.5 Conformity assessment activities		
4.5.1 first indent Annex VII	Procedures for planning the conduct of each individual project	
Title and Revision Document 1	*Comment*	
Title and Revision Document 2	*Comment*	
4.5.1 second indent Annex VII	Procedures for the rotation of the members of the assessment team at appropriate intervals	Annex IX 3.6
Title and Revision Document 1	*Comment*	
Title and Revision Document 2	*Comment*	
4.5.1 third indent Annex VII	Procedures specifying the rationale for fixing time limits for completion of the conformity assessment	
Title and Revision Document 1	*Comment*	
Title and Revision Document 2	*Comment*	
4.5.1 Fourth and fifth indents Annex VII	Procedures for the assessment of the manufacturer's technical documentation including review of manufacturer's procedures and documentation relating to performance evaluation	Annex VII 4.5.3 4.5.4
Title and Revision Document 1	*Comment*	
Title and Revision Document 2	*Comment*	
4.5.1 sixth indent Annex VII	Procedures for the assessment of the interface between the manufacturer’s risk management process and its appraisal and analysis of the performance evaluation	
Title and Revision Document 1	*Comment*	
Title and Revision Document 2	*Comment*	
4.5.1 seventh indent Annex VII	Procedures to carry out the specific procedures referred to in Sections 5 of Annex IX	
Title and Revision Document 1	*Comment*	
Title and Revision Document 2	*Comment*	
4.5.1 eighth indent Annex VII	In the case of class B or class C devices, procedures to assess the technical documentation of devices selected on a representative basis	Article 48 Annex VII 4.5.2 Annex IX 2.3 3.5 MDCG 2019-13
Title and Revision Document 1	*Comment*	
Title and Revision Document 2	*Comment*	

4.5.1 ninth and tenth indents Annex VII	Procedures to plan and periodically carry out appropriate surveillance audits and assessments, carry out or request certain tests to verify the proper functioning of the quality management system, to perform unannounced on site audits, and to verify that the manufactured device is in conformity with the technical documentation	Annex VII 4.10
Title and Revision Document 1	*Comment*	
Title and Revision Document 2	*Comment*	
4.5.1 eleventh indent Annex VII	Procedures to evaluate and verify a manufacturer's compliance with relevant Annexes	
Title and Revision Document 1	*Comment*	
Title and Revision Document 2	*Comment*	
4.5.1 Last paragraph Annex VII	Procedures to take into consideration available CS, guidance and best practice documents and harmonised standards	MDCG 2019-6 Q IV.11
Title and Revision Document 1	*Comment*	
Title and Revision Document 2	*Comment*	
4.5.2 Quality management system auditing		
4.5.2 Annex VII	<u>Procedures for the assessment of quality management systems, according to each specific conformity assessment activity covered by the application and the class of the device, including:</u> - Drawing-up audit programmes - Auditing the various manufacturing sites, suppliers and/or subcontractors - Drawing-up audit plans - Drawing-up sampling plans for classes B and C - Selection of site auditors	Annex IX Chapter I MDCG 2019-6 Q IV.2 MDCG 2019-13 MDCG 2022-17
Title and Revision Document 1	*Comment*	
Title and Revision Document 2	*Comment*	
4.5.3. Product verification		
4.5.3 Assessment of the technical documentation Annex VII	<u>Procedures to assess the manufacturer's technical documentation, including:</u> - Allocations of personnel - Conformity of the design - Examination of the implementation by manufacturers of incoming, in-process and final checks - Physical or laboratory tests, if required	Article 48 Annex II Annex III Annex IX Chapter II
Title and Revision Document 1	*Comment*	
Title and Revision Document 2	*Comment*	

4.5.3 Type-examinations Annex VII	Procedures to examine and assess the manufacturer's technical documentation and verify the type, including establishment of tests plans	Annex X
Title and Revision Document 1	*Comment*	
Title and Revision Document 2	*Comment*	
4.5.3 Verification by examination and testing of every product batch Annex VII	Documentation relating to verification by examination and testing of every product batch, including establishment of test plans	Annex IX Annex XI
Title and Revision Document 1	*Comment*	
Title and Revision Document 2	*Comment*	
4.5.4 Performance evaluation assessment		
4.5.4 Annex VII	Procedures for the review of the manufacturer's procedures and documentation relating to performance evaluation, including the validation of the summary of safety and performance (for class C and D) and the upload of the summary to EUDAMED	Article 29 Article 56 Annex II 6.1; 6.2 Annex XIII MDCG 2022-2 MDCG 2022-9
Title and Revision Document 1	*Comment*	
Title and Revision Document 2	*Comment*	
4.5.5 Specific Procedures		
4.5.5 Annex VII	<u>Documentation relating to documented procedures, expertise and facilities to carry out the specific procedures:</u> - Assessment of devices for self-testing and near-patient testing (5.1 Annex IX) - Consultation to expert panel for certain class D devices (Article 48.6, 4.9 Annex IX and 3(j) Annex X) - Consultation to medicinal products authority for companion diagnostics (5.2 Annex IX) - Batch verification for class D devices (4.12 Annex IX and 5.1 Annex XI)	Article 50 Annex IX Sections 4 and 5 Annex XI Section 5 MDCG 2021-4 MDCG 2021-22 MDCG 2022-3
Title and Revision Document 1	*Comment*	
Title and Revision Document 2	*Comment*	

4.6 Reporting		
4.6 Annex VII	Documentation detailing how all steps of the conformity assessment are documented and relevant templates of reports/records, in particular: - Records related to QMS audits - Technical Documentation Assessment Report (TDAR) - Performance Evaluation Assessment report (PEAR) - Detailed report for each specific project, including the recommendation for a final review and for a final decision - Procedure to provide the report to the manufacturer in question	
Title and Revision Document 1	*Comment*	
Title and Revision Document 2	*Comment*	
4.7 Final review		
4.7 Annex VII	Documentation relating to the final review process carried out prior to making a final decision	
Title and Revision Document 1	*Comment*	
Title and Revision Document 2	*Comment*	
4.8 Decisions and Certifications		
4.8 Annex VII	Documentation relating to the final decision process, including: - Procedures for decision-making for the issuance, suspension, restriction and withdrawal of certificates - Certificate templates intended to be used for the different types of conformity assessments for which the CAB seeks designation - Notification of the outcome of the assessment and the resultant decision to the manufacturer and EUDAMED	Articles 51 and 52(g) Annex XII MDCG 2018-8 MDCG 2019-6 Q IV.3 Q IV.6 Q IV.8
Title and Revision Document 1	*Comment*	
Title and Revision Document 2	*Comment*	
4.9 Changes and modifications		
4.9 Annex VII	Documentation detailing manufacturers' information obligations and the CAB's assessment of changes, including documented procedures and contractual arrangements	MDCG 2019-6 Q IV.9
Title and Revision Document 1	*Comment*	
Title and Revision Document 2	*Comment*	

4.10 Surveillance activities and post-certification monitoring		
4.10 Annex VII	Documentation detailing the following:	
Screening	Procedures for screening of relevant sources of scientific and clinical data and post-market information relating to the scope of designation	
Title and Revision Document 1	*Comment*	
Title and Revision Document 2	*Comment*	
Surveillance activities	<u>Procedures in relation to surveillance activities, in particular to:</u> - Define how and when surveillance activities of manufacturers are to be conducted (on at least an annual basis) - Conduct unannounced on-site audits - Assessment of the documentation on vigilance, PMS and PMPF - Sample and test devices and technical documentation - Impose specific restrictions on the relevant certificate, or suspend or withdraw it	Annex IX Sections 3.3 and 3.4 Annex XI Section 4 MDCG 2019-6 Q IV.10
Title and Revision Document 1	*Comment*	
Title and Revision Document 2	*Comment*	
Vigilance	Procedures to review vigilance data which the NB has access under Article 87(2) and estimating the impact on issued certificates, including the recording of the results of the evaluation and any decisions taken	
Title and Revision Document 1	*Comment*	
Title and Revision Document 2	*Comment*	
PSUR	Documentation relating to the review of periodic safety update reports	Article 81
Title and Revision Document 1	*Comment*	
Title and Revision Document 2	*Comment*	
Conditions	Procedures related to conditions for certification	
Title and Revision Document 1	*Comment*	
Title and Revision Document 2	*Comment*	
4.11 Re-certification		
4.11 Annex VII	Documentation detailing the conduct of re-certification reviews and the renewal of certificates	MDCG 2019-6 Q IV.12
Title and Revision Document 1	*Comment*	
Title and Revision Document 2	*Comment*	
Article 53	Documentation relating to voluntary changes of a notified body	MDCG 2018-8 MDCG 2019-6 Q IV.4
Title and Revision Document 1	*Comment*	
Title and Revision Document 2	*Comment*	

List of documents submitted with the application

Please update and send in with every new submission

G.1 Scope of designation requested under the IVDR	Original submission (with application, version and date)	2nd submission (version and date)	3rd submission (version and date)
MDCG 2021-18			
Title and Revision Document 2			
G.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 1.1.1			
Title and Revision Document 1			
Title and Revision Document 2			
G.3 Valid accreditation certificate and the corresponding evaluation report as referred to in Article 34(2) of Regulation (EU) 2017/746			
Title and Revision Document 1			
Title and Revision Document 2			
1. ORGANISATIONAL AND GENERAL REQUIREMENTS			
1.1 Legal status and organisational structure			
1.1.1 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			
Title and Revision Document 1			
Title and Revision Document 2			
1.1.2 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			
Title and Revision Document 1			
Title and Revision Document 2			
1.1.3 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 owns the conformity assessment body, and the legal and operational relationships with the conformity assessment body			
Title and Revision Document 1			
Title and Revision Document 2			
1.1.4 - 1.1.5 Documentation describing the organisational structure, the allocation of responsibilities, reporting lines and the operational management conformity assessment body			
Title and Revision Document 1			
Title and Revision Document 2			
1.1.6 Documentation detailing the functions, responsibilities and authorities of the top-level management, indicating the overall authority and			

responsible person for each of the following:			
Provision of adequate resources for conformity assessment activities			
Development of procedures and policies for the operation of the notified body			
Supervision of implementation of the procedures, policies and quality management systems of the notified body			
Supervision of the notified body's finances			
Activities and decisions taken by the notified body, including contractual agreements			
Delegation of authority to personnel and/or committees, where necessary, for the performance of defined activities			
Interaction with the authority responsible for notified bodies and the obligations regarding communications with other competent authorities, the Commission and other notified bodies			
Individual having overall responsibility for all conformity assessment activities in relation to devices (head of the notified body)			
1.2 Independence and impartiality			
1.2.1 - 1.2.2 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 whole organisation (e.g. corporate group), personnel and activities, including procedures providing for the identification, investigation and resolution of any case in which a conflict of interest may arise			
Personnel commitment and written statement			
Title and Revision Document 2			
1.2.3 -1.2.7 Independence of the notified body, the larger organisation to which it belongs, the top-level management and conformity assessment personnel: Documentation on ensuring independence and impartiality			
Title and Revision Document 1			
Title and Revision Document 2			
1.2.8 Documentation demonstrating how the conformity assessment body operates with a set of consistent, fair and reasonable terms and conditions, taking into account small and medium size businesses			
Title and Revision Document 1			
Title and Revision Document 2			
1.3 Confidentiality			
1.3.1 - 1.3.2 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 and secrecy of the information (including proprietary rights) which comes into their possession			
Personnel commitment and written statement			
Title and Revision Document 2			
1.4 Liability			
1.4.1 - 1.4.2 Documentation on the liability insurance covering conformity assessment activities, including its scope and overall financial value			
Title and Revision Document 1			
Title and Revision Document 2			
1.5 Financial requirements			
1.5 Documentation detailing the conformity assessment body's financial resources, including its financial capacity and long-term economic viability			
Title and Revision Document 1			
Title and Revision Document 2			
1.6 Participation in coordination activities			
1.6.1 – 1.6.2 Documentation on the CAB's procedures ensuring its personnel is involved in standardisation activities and in the work of the notified body coordination group and how personnel are informed. Strategy to take into consideration guidance and best practice documents			
Title and Revision Document 1			
Title and Revision Document 2			

2. QUALITY MANAGEMENT REQUIREMENTS			
2.1 - 2.2 i) Management system structure and the list of all quality management system documents, including policies and objectives			
Title and Revision Document 1			
Title and Revision Document 2			
2.2 ii) Policies for assignment of activities and responsibilities to personnel			
Title and Revision Document 1			
Title and Revision Document 2			
2.2 iii) Documentation detailing the assessment and decision-making processes in accordance with the tasks, responsibilities and role of the notified body's personnel and top-level management			
Title and Revision Document 1			
Title and Revision Document 2			
2.2 iv) Documentation detailing the planning, conduct, evaluation and, if necessary, adaptation of the conformity assessment procedures			
Title and Revision Document 1			
Title and Revision Document 2			
2.2 v) Procedures for control of documents including verification that the documents have the same content where documents are used in different languages			
Title and Revision Document 1			
Title and Revision Document 2			
2.2 vi) Procedures for control of records			
Title and Revision Document 1			
Title and Revision Document 2			
2.2 vii) Procedures for management review			
Title and Revision Document 1			
Title and Revision Document 2			
2.2 viii) Procedures for internal audits			
Title and Revision Document 1			
Title and Revision Document 2			
2.2 ix) Procedures for corrective and preventive actions			
Title and Revision Document 1			
Title and Revision Document 2			
2.2 x) Procedures for complaints and appeals			
Title and Revision Document 1			
Title and Revision Document 2			
2.2 xi) Procedures for continuous training			
Title and Revision Document 1			

Title and Revision Document 2			
2.3 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			
Title and Revision Document 1			
Title and Revision Document 2			
2.4 Model declaration of commitment of the CAB's personnel to comply with the procedures			
Title and Revision Document 1			
Title and Revision Document 2			
Articles 32.2; 40.2; 40.3	Procedures on the NB's obligation to make available and submit upon requests all relevant documentation		
Title and Revision Document 1			
Title and Revision Document 2			
Articles 40.1; 42.3; 42.5; 42.9	Procedures for information to the authority responsible for NBs of relevant changes and ceasing of activities		
Title and Revision Document 1			
Title and Revision Document 2			

3. RESOURCE REQUIREMENTS			
3.1 General			
3.1.1 Documentation detailing the CAB's: - Equipment, facilities and competence (including testing facilities) needed to perform properly the technical, scientific and administrative tasks - Permanent availability of personnel and in sufficient numbers - Sufficient internal competence to critically evaluate assessments conducted by external expertise (3.4.3)			
Title and Revision Document 1			
Title and Revision Document 2			
3.1.2 Documentation detailing the implementation of a system for exchange of experience and a continuous training and education programme			
Title and Revision Document 1			
Title and Revision Document 2			
3.1.3 Documentation detailing: - The extent and limits of duties and responsibilities of the personnel - The level of authorisation of the personnel - The process for informing the personnel accordingly			
Title and Revision Document 1			
Title and Revision Document 2			
3.2 Qualification criteria in relation to personnel			
3.2.1 – 3.2.2 Documentation detailing: - Process to establish and document the qualification criteria (providing a sufficient level of detail for the required qualification within the subdivisions of the applied-for scope) - Process for selection and authorisation of personnel, including the required initial and ongoing training			
Title and Revision Document 1			
Title and Revision Document 2			
3.2.2 – 3.2.7 - Specific qualification criteria (3.2.2); Qualification criteria per role: - Personnel responsible for establishing qualification criteria and for authorising other personnel (3.2.3) - Personnel with relevant clinical expertise (Internal clinician/Clinical specialist) (3.2.4) - Product reviewers (3.2.5) - Site auditors (3.2.6) - Final reviewers and decision-makers (3.2.7)			
Title and Revision Document 1			
Title and Revision Document 2			
3.3 Documentation of qualification, training and authorisation of personnel			

3.3.1 Procedure in place to fully document the qualification of each member of personnel and the satisfaction of the qualification criteria			
Title and Revision Document 1			
Title and Revision Document 2			
3.3.2 i) Matrix detailing the authorisations (including any limitations) and responsibilities of the personnel, including employment status (e.g. full-time, external, etc.) and location of all internal and external personnel			
Title and Revision Document 1			
Title and Revision Document 2			
3.3.2 ii) Model/template of the record attesting authorisation of qualified personnel; the records shall contain a rationale for defining the scope of the responsibilities for each of the assessment personnel and records of the conformity assessment activities carried out by each of them Representative sample of records (at least one per role/function) demonstrating compliance with the qualification criteria for the authorisation of the personnel member (mock file or blacked out document might be acceptable)			
Title and Revision Document 1			
Title and Revision Document 2			
3.4 Subcontractors and external experts			
3.4.1 Lists of all subcontractors and subsidiaries, 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			
Title and Revision Document 1			
Title and Revision Document 2			
3.4.2 Documentation detailing the conditions under which subcontracting may take place			
Title and Revision Document 1			
Title and Revision Document 2			
3.5 Monitoring of competences, training, exchange of experience			
3.5.1 - 3.5.2 <u>Documentation detailing:</u> -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 - How the personnel is aware of Union and national law in force on devices, relevant harmonised standards, CS, guidance documents and the results of the coordination activities of NBCG-Med - Verification that personnel takes part in the internal exchange of experience and the continuous training and education programme			
Title and Revision Document 1			
Title and Revision Document 2			

4. PROCESS REQUIREMENTS			
4.1 General			
4.1 i) Overview of processes for the conduct of each conformity assessment activity comprising the individual steps from pre-application activities up to decision-making and surveillance, e.g. flowcharts			
Title and Revision Document 1			
Title and Revision Document 2			
4.1 ii) Documentation detailing the internal activities of the CAB which shall not be subcontracted			
Title and Revision Document 1			
Title and Revision Document 2			
4.2 Notified body quotations and pre-application activities			
4.2 (a) Description of the application procedure by which manufacturers can obtain certification, including which languages are acceptable			
Title and Revision Document 1			
Title and Revision Document 2			
4.2 (b) Procedures relating to fees charged and financial conditions			
Title and Revision Document 1			
Title and Revision Document 2			
4.2 (c) Procedures in relation to advertising of conformity assessment services			
Title and Revision Document 1			
Title and Revision Document 2			
4.2 (d) Procedures relating to the review of pre-application information			
Title and Revision Document 1			
Title and Revision Document 2			
4.2 (e) Procedures to ensure that all contracts relating to the conformity assessment activities are concluded directly between the manufacturer and the conformity assessment body			
Title and Revision Document 1			
Title and Revision Document 2			
4.3 Application review and contract			
4.3 i) Template application form			
Title and Revision Document 1			
Title and Revision Document 2			
4.3 ii) Template contract including terms and conditions and obligations of the CAB in relation to conformity assessment activities. Terms and conditions might be in a separate annex to the contract template			
Title and Revision Document 1			

Title and Revision Document 2			
4.3 (a)–(e) Procedures relating to review of applications, including documented outcome of each review and notification to EUDAMED of refusals or withdrawals of applications			
Title and Revision Document 1			
Title and Revision Document 2			
4.4 Allocation of resources			
4.4 i) Procedures and forms to ensure that conformity assessment activities are conducted by appropriately qualified and authorised personnel, and that allocation of tasks and changes thereto are documented			
Title and Revision Document 1			
Title and Revision Document 2			
4.4 ii) Procedures and forms to identify one individual responsible for each application			
Title and Revision Document 1			
Title and Revision Document 2			
4.5 Conformity assessment activities			
4.5.1 i) Procedures for planning the conduct of each individual project			
Title and Revision Document 1			
Title and Revision Document 2			
4.5.1 ii) Procedures for the rotation of the members of the assessment team at appropriate intervals			
Title and Revision Document 1			
Title and Revision Document 2			
4.5.1 iii) Procedures specifying the rationale for fixing time limits for completion of the conformity assessment			
Title and Revision Document 1			
Title and Revision Document 2			
4.5.1 iv-v) Procedures for the assessment of the manufacturer's technical documentation including review of manufacturer's procedures and documentation relating to the evaluation of performance evaluation			
Title and Revision Document 1			
Title and Revision Document 2			
4.5.1 vi) Procedures for the assessment of the interface between the manufacturer’s risk management process and its appraisal and analysis of the performance evaluation			
Title and Revision Document 1			
Title and Revision Document 2			
4.5.1 vii) Procedures to carry out the specific procedures referred to in Sections 5 of Annex IX			
Title and Revision Document 1			
Title and Revision Document 2			

4.5.1 viii) In the case of class B or class C devices, procedures to assess the technical documentation of devices selected on a representative basis			
Title and Revision Document 1			
Title and Revision Document 2			
4.5.1 ix-x) Procedures to plan and periodically carry out appropriate surveillance audits and assessments, carry out or request certain tests to verify the proper functioning of the quality management system, to perform unannounced on site audits, and to verify that the manufactured device is in conformity with the technical documentation			
Title and Revision Document 1			
Title and Revision Document 2			
4.5.1 xi) Procedures to evaluate and verify a manufacturer's compliance with relevant Annexes			
Title and Revision Document 1			
Title and Revision Document 2			
4.5.1 Last paragraph - Procedures to take into consideration available CS, guidance and best practice documents and harmonised standards			
Title and Revision Document 1			
Title and Revision Document 2			
4.5.2 Quality management system auditing			
4.5.2 Procedures for the assessment of quality management systems, according to each specific conformity assessment activity covered by the application and the class of the device			
Title and Revision Document 1			
Title and Revision Document 2			
4.5.3 Product verification			
4.5.3 Procedures to assess the manufacturer’s technical documentation			
Title and Revision Document 1			
Title and Revision Document 2			
4.5.3 Procedures to examine and assess the manufacturer’s technical documentation and verify the type, including establishment of test plans			
Title and Revision Document 1			
Title and Revision Document 2			
4.5.3 Documentation relating to verification by examination and testing of every product batch, including establishment of test plans			
Title and Revision Document 1			
Title and Revision Document 2			
4.5.4 Performance evaluation assessment			
4.5.4 Procedures for the review of the manufacturer’s procedures and documentation relating to performance evaluation, including the			

validation of the summary of safety and performance (class C and D) and the upload of the summary to EUDAMED			
Title and Revision Document 1			
Title and Revision Document 2			
4.5.5 Specific Procedures			
4.5.5 Documentation relating to documented procedures, expertise and facilities to carry out the specific procedures			
Title and Revision Document 1			
Title and Revision Document 2			
4.6 Reporting			
4.6 Documentation detailing how all steps of the conformity assessment are documented and relevant templates of reports/records			
Title and Revision Document 1			
Title and Revision Document 2			
4.7 Final review			
4.7 Documentation relating to the final review process carried out prior to making a final decision			
Title and Revision Document 1			
Title and Revision Document 2			
4.8 Decisions and Certifications			
4.8 Documentation relating to the final decision process			
Title and Revision Document 1			
Title and Revision Document 2			
4.9 Changes and modifications			
4.9 Documentation detailing manufacturers' information obligations and the CAB's assessment of changes, including documented procedures and contractual arrangements			
Title and Revision Document 1			
Title and Revision Document 2			
4.10 Surveillance activities and post-certification monitoring			
4.10 Procedures for screening of relevant sources of scientific and clinical data and post-market information relating to the scope of designation			
Title and Revision Document 1			
Title and Revision Document 2			
4.10 Procedures in relation to surveillance activities			

Title and Revision Document 1			
Title and Revision Document 2			
4.10 Procedures to review vigilance data which the NB has access under Article 87(2) and estimating the impact on issued certificates, including the recording of the results of the evaluation and any decisions taken			
Title and Revision Document 1			
Title and Revision Document 2			
4.10 Documentation relating to the review of periodic safety update reports			
Title and Revision Document 1			
Title and Revision Document 2			
4.10 Procedures related to conditions for certification			
Title and Revision Document 1			
Title and Revision Document 2			
4.11 Re-certification			
4.11 Documentation detailing the conduct of re-certification reviews and the renewal of certificates			
Title and Revision Document 1			
Title and Revision Document 2			
Article 53 Documentation relating to voluntary changes of a notified body			
Title and Revision Document 1			
Title and Revision Document 2			