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 APPL	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.

²In 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.

Medical Device Coordination Group Document

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
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MDCG 2024-8

OUTCOME OF THE RE	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 onsite assessment can be envisaged ⁶	to be clarified <u>before</u> an		
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. GENERA	G. GENERAL DOCUMENTATION			
List of com	ments on single doc	uments ⁷		
G.1 Scope of	of designation request	ed under the IVDR		
MDCG 2021	1-18	Comment		
Title and Re	evision Document 2	Comment		
		conformity assessment body by the person who has subrunless such authorisation follows from the documentation		
Title and Re	evision Document 1	Comment		
Title and Re	evision Document 2	Comment		
	ccreditation certificate in (EU) 2017/746	and the corresponding evaluation report as referred to in A	Article 34(2)	
Title and Re	evision Document 1	Comment		
Title and Re	evision Document 2	Comment		
1. ORGANI	SATIONAL AND GEN	IERAL REQUIREMENTS		
List of com	ments on single doc	uments ⁷		
1.1 Legal st	tatus and organisatio	onal structure		
1.1.1 Annex VII	and its status, includi	ling the conformity assessment body's legal personality ing information about ownership and the legal or natural ontrol over the conformity assessment body	MDCG 2019-6 ⁸ Q I.2	
Title and Re	evision Document 1	Comment		
	evision Document 2	Comment		
1.1.2 Annex VII	conformity assessme	ling the activities of the organisation to which the ent body belongs, the organisational structure and	MDCG 2019-6	
		rganisation, and its relationship with the conformity	Q I.3	
	assessment body		Q I.4	
Title and De	vision Doormant 1	Commont	ζ	
	evision Document 1 evision 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 Re	evision Document 1	Comment		
Title and Re	evision Document 2	Comment		

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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.

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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		
7			Q I.4
	vision Document 1	Comment	
Title and Re	vision 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:		
	adequate resources ty assessment	Responsible person (position or role, no individual name Relevant documents and Comment)
	nt of procedures and he operation of the	Responsible person (position or role, no individual name Relevant documents and Comment)
Supervision the procedure quality mana the notified b	of implementation of res, policies and agement systems of body	Responsible person (position or role, no individual name Relevant documents and Comment	
Supervision body's finance	of the notified ces	Responsible person (position or role, no individual name Relevant documents and Comment)
	d decisions taken by body, including 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)	
responsible and the obliq communicat competent a	vith the authority for notified bodies gations regarding ions with other authorities, the and other notified	Responsible person (position or role, no individual name Relevant documents and Comment)
Individual har responsibility assessment	aving overall y for all conformity activities in relation nead of the notified	Responsible person (position or role, no individual name) Relevant documents and Comment	Annex VII 3.1.1 Last paragraph
1.2 Indepen	dence and impartial	ity	
1.2.2 conformity assessment body has in place to		ling the structures, policies and procedures the ent body has in place to safeguard and promote the dence, impartiality and objectivity throughout its whole	Annex VII 1.1.2
Annex VII	organisation (e.g. co	orporate group), personnel and activities, including g for the identification, investigation and resolution of any	MDCG 2019-6
	Case III WIIICH a CUIIII	not of interest may arise	Q I.3
			Q I.4
			Q 1.5
			Q 1.9
	ommitment and	Comment	Annex VII
written state		Commont	2.4
Title and Re	vision Document 2	Comment	

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1.2.3 - Independence of the notified body, the larger organisation to which it belongs, the top-level management and conformity assessment personnel 49.5 - Annex VII Documentation on ensuring independence and impartiality with respect to: - IVD Medical device industry (1.2.3) - 1.2.4) - 1.2.9 - 1.2.9 - Remuneration (1.2.5) - Declarations of interest by top-level management (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) - Q.1.3 - Q.1.4 - Q.1.5 - Q.1.6 - Q.1.8 - Q.1.8 - Q.1.9 - Q.			•		
- 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) - Public ownership (1.2.6) - Subsidiaries, subcontractors and external experts (1.2.7; 3.4.2) Title and Revision Document 1 Comment Title and Revision Document 2 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 2 Comment 1.3.2 Confidentiality 1.3.1 - 1.3.2 Confidentiality 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 Comment 1.4.1 Liability Documentation on the liability insurance covering conformity assessment activities, including its scope and overall financial value Documentation detailing the conformity assessment body's financial resources, including its financial requirements 1.5 Documentation detailing the conformity assessment body's financial resources, including its financial requirements Title and Revision Document 1 Comment Title and Revision Document 2 Comment Title and Revision Document 1 Comment Title and Revision Document 2 Comment Title and Revision Document 1 Comment					
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- Public ownership (1.2.6) - Subsidiaries, subcontractors and external experts (1.2.7; 3.4.2) - Subsidiaries, subcontractors and external experts (1.2.7; 3.4.2) - Subsidiaries, subcontractors and external experts (1.2.7; 3.4.2) - Q I.3 - Q I.4 - Q I.5 - Q I.6 - Q I.8 - Q I.9 - Title and Revision Document 1		`			
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Title and Revision Document 2			Comment		
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Title and Revision Document 2	Annex VII			Q I.10	
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Annex VII its financial capacity and long-term economic viability Title and Revision Document 1 Comment	1.5 Financi	al requirements			
Annex VII its financial capacity and long-term economic viability Title and Revision Document 1 Comment	1.5	Documentation detail	ling the conformity assessment body's financial resources	. includina	
		its financial capacity and long-term economic viability			
Title and Revision Document 2 Comment					
	Title and Re	evision Document 2	Comment		

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1.6 Particip	1.6 Participation in coordination activities			
1.6.1 - 1.6.2		e CAB's procedures ensuring its personnel is involved in ties and in the work of the notified body coordination	Article 45	
Annex VII				
Title and Re	Title and Revision Document 1 Comment			
Title and Revision Document 2 Comment				

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2. QUALITY	MANAGEMENT RE	QUIREMENTS	
List of com	ments on single doo	cuments 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		
	evision Document 1	Comment	
2.2 second indent Annex VII	Policies for assignment	Comment ent of activities and responsibilities to personnel	
	vision Document 1	Commont	
	evision Document 1 evision Document 2	Comment Comment	
2.2 third indent Annex VII	with the tasks, responsibilities and role of the notified body's personnel and top-level		
	evision Document 1 evision Document 2	Comment Comment	
2.2 fourth indent Annex VII	the conformity asses	iling the planning, conduct, evaluation and, if necessary, assment procedures	daptation of
	evision Document 1	Comment	
Title and Re	evision Document 2	Comment	
2.2 fifth indent Annex VII		ol of documents including verification that the documents ent where documents are used in different languages	Annex VII 2.2 Last
			paragraph
Title and Re	evision Document 1	Comment	
Title and Re	evision Document 2	Comment	
2.2 sixth indent Annex VII	Procedures for contr	ol of records	
Title and Re	evision Document 1	Comment	
	evision Document 2	Comment	
2.2 seventh indent	Procedures for mana	agement review	
Annex VII			
	evision Document 1	Comment	
Title and Re	evision Document 2	Comment	

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Medical Device Coordination Group Document

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2.2 eighth indent	Procedures for intern	al audits	
Annex VII			
Title and Re	evision Document 1	Comment	
	evision Document 2	Comment	
2.2 ninth indent	Procedures for correc	ctive and preventive actions	
Annex VII			
Title and Re	evision Document 1	Comment	
Title and Re	evision Document 2	Comment	
2.2 tenth indent	Procedures for comp	laints and appeals	
Annex VII			
	evision Document 1	Comment	
Title and Re	evision Document 2	Comment	
2.2 eleventh	Procedures for contir	nuous training	Annex VII
indent Annex VII			3.5.2
Title and Re	evision Document 1	Comment	
Title and Re	evision Document 2	Comment	
2.3 Annex VII	management system	ng to the implementation and maintenance of the qu throughout the conformity assessment body's organ and subcontractors involved in conformity assessm	nisation,
Title and Re	evision Document 1	Comment	
Title and Re	evision Document 2	Comment	
2.4 Annex VII	Model declaration of	commitment of the CAB's personnel to comply with	the procedures
	evision Document 1 evision Document 2	Comment Comment	
Articles 32.2 40.2		B's obligation to make available and submit upon re	quests all
40.3			
	evision Document 1 evision Document 2	Comment Comment	
Articles 40.1	Procedures on the Ni activities	B's obligation for information of relevant changes an	d ceasing of
42.3			
42.5			
42.9			
	evision Document 1	Comment	
Tille and Re	evision Document 2	Comment	

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3. RESOURCE REQUIREMENTS			
List of com	ments on single doc	uments ¹⁰	
3.1 Genera	I		
3.1.1	Documentation detai	ling the CAB's:	Article
Annex VII		s and competence (including testing facilities) needed to technical, scientific and administrative tasks	32.1
		lity of personnel and in sufficient numbers, including ment and other contracts used for the personnel	MDCG 2019-6 Q III.2
	- Sufficient internal coupling by external expertise	ompetence to critically evaluate assessments conducted (3.4.3)	Q III.3
	evision Document 1 evision Document 2	Comment Comment	•
3.1.2 Annex VII		ling the implementation of a system for exchange of experience and education programme	ence and
	evision Document 1	Comment	
Title and Re	evision Document 2	Comment	
3.1.3	Documentation detai	<u>ling:</u>	
Annex VII	- The extent and limit subcontractors and e	ts of duties and responsibilities of the personnel, including external experts	
	- The level of authori	sation of the personnel	
	- The process for info	ormation the personnel accordingly	
	evision Document 1 evision Document 2	Comment Comment	
3.2 Qualific	ation criteria in relat	ion to personnel	
3.2.1 -	Documentation detai	ling:	NBOG
3.2.2 Annex VII		h and document the qualification criteria (providing a ail for the required qualification within the subdivisions of	BPG 2017-2
	- Process for selection initial and ongoing tra	on and authorisation of personnel, including the required aining	
	evision Document 1 evision Document 2	Comment Comment	

¹⁰ 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.

Annex VII

Medical Device Coordination Group Document MDCG 2024-8 3.2.2 -- Specific qualification criteria (3.2.2) Article 3.2.7 32.1 Qualification criteria per role: (employed Annex VII by) - Personnel responsible for establishing qualification criteria and for authorising other personnel (3.2.3) **NBOG** - Personnel with relevant clinical expertise (Internal clinician/Clinical specialist) **BPG** (3.2.4)2017-2 - Product reviewers (3.2.5) **MDCG** - Site auditors (3.2.6) 2019-6 Q III.4 - Final reviewers and decision-makers (3.2.7) QIII.6 QIII.7 O.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 Procedure in place to fully document the qualification of each member of **NBOG** personnel and the satisfaction of the qualification criteria BPG Annex VII 2017-2 **MDCG** 2019-6 Q III.1 Title and Revision Document 1 Comment Title and Revision Document 2 Comment 3.3.2 first Matrix detailing the authorisations (including any limitations) and **MDCG** indent responsibilities of the personnel, including employment status (e.g. full-time, 2021-14 external, etc.) and location of all internal and external personnel; the Annex VII authorisations shall be specified by using the codes set out in the Commission Implementing Regulation on codes and corresponding types of devices Title and Revision Document 1 Comment Title and Revision Document 2 Comment 3.3.2 Model/template of the record attesting authorisation of qualified personnel; the records second shall contain a rationale for defining the scope of the responsibilities for each of the indent assessment personnel and records of the conformity assessment activities carried out by each of them Annex VII 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 Lists of all subcontractors and subsidiaries, including a description of their Article 33

Contractual arrangem	ens in place	
Title and Revision Document 1	Comment	
Title and Revision Document 2	Comment	

functions in relation to conformity assessment activities (e.g. external

contractual arrangements in place

laboratories) or administrative tasks (e.g. information technologies) and

Article

52(a)

Medical Device Coordination Group Document

3.4.2 Annex VII	Documentation detail	ing the conditions under which subcontracting may take	place
Title and Re	evision Document 1 evision Document 2 ring of competences,	Comment Comment training, exchange of experience	
3.5.1 - 3.5.2 Annex VII	competence of the in identification of training. - How the personnel relevant harmonised the coordination active. - Verification that per	n, on-going monitoring and periodic review of sternal and external personnel, including the sing needs and drawing up of training plans is aware of Union and national law in force on devices, standards, CS, guidance documents and the results of	Article 45 MDCG 2019-6 Q III.5
Title and Revision Document 1 Comment Title and Revision Document 2 Comment			

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4. PROCESS REQUIREMENTS						
List of com	List of comments on single documents ¹¹					
4.1 General	l					
4.1 1 st paragraph Annex VII	activity comprising th	es for the conduct of each conformity assessme individual steps from pre-application activitie surveillance, e.g. flowcharts		Annex VII 2.1		
Title and Re	evision Document 1	Comment		1		
Title and Re	evision Document 2	Comment				
4.1 2 nd paragraph Annex VII	Documentation detai subcontracted	ling the internal activities of the CAB which sha	all not be	MDCG 2019-6 Q III.6		
Title and Re	evision Document 1	Comment		1		
Title and Re	evision Document 2	Comment				
4.2 Notified	l body quotations an	d pre-application activities				
4.2 (a) Annex VII		plication procedure by which manufacturers ca g which languages are acceptable	an obtain	MDCG 2019-6 Q I.6		
Title and Re	evision Document 1	Comment				
	evision Document 2	Comment				
4.2 (b)	Procedures relating t	o fees charged and financial conditions		Article 46		
Annex VII				MDCG 2019-6 Q V.2		
				MDCG 2023-2		
	evision Document 1	Comment				
Title and Re	evision Document 2	Comment				
4.2 (c) Annex VII	Procedures in relatio	n to advertising of conformity assessment serv	rices			
	evision Document 1	Comment				
Title and Re	evision Document 2	Comment				
4.2 (d) Annex VII	Procedures relating t	to the review of pre-application information	Manual o	n borderline ification		
AUTOX VII			MDCG 20)20-16		
	evision Document 1 evision Document 2	Comment Comment				

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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.

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	that all contracts relating to the conformity assessment tween the manufacturer and the conformity assessment	
vision Document 1	Comment	
Template application	form	MDCG
		2019-6
		Q 1.7
evision Document 1	Comment	
conformity assessmenthe contract template	nt activities (terms and conditions might be in a separate)	
	Comment	
vision Document 2	Comment	
Procedures relating to	review of applications, including documented	Article 49.2
		Application
withdrawals of applica	ations	sections in Annex IX-XI
vision Document 1	Comment	
vision Document 2	Comment	
on of resources		
		Annex VII
Procedures and forms conducted by appropri	s to ensure that conformity assessment activities are riately qualified and authorised personnel, and that d changes thereto are documented	Annex VII 4.5.1 second indent
Procedures and forms conducted by appropri	s to ensure that conformity assessment activities are riately qualified and authorised personnel, and that	4.5.1 second
Procedures and forms conducted by appropri	s to ensure that conformity assessment activities are riately qualified and authorised personnel, and that	4.5.1 second indent MDCG 2019-6
Procedures and forms conducted by appropri	s to ensure that conformity assessment activities are riately qualified and authorised personnel, and that	4.5.1 second indent MDCG 2019-6 Q IV.6
Procedures and forms conducted by appropri	s to ensure that conformity assessment activities are riately qualified and authorised personnel, and that	4.5.1 second indent MDCG 2019-6
Procedures and forms conducted by approprial allocation of tasks and	s to ensure that conformity assessment activities are riately qualified and authorised personnel, and that	4.5.1 second indent MDCG 2019-6 Q IV.6
Procedures and forms conducted by approprial allocation of tasks and evision Document 1	s to ensure that conformity assessment activities are riately qualified and authorised personnel, and that d changes thereto are documented Comment	4.5.1 second indent MDCG 2019-6 Q IV.6 Q IV.7
Procedures and forms conducted by approprial allocation of tasks and	s to ensure that conformity assessment activities are riately qualified and authorised personnel, and that d changes thereto are documented	4.5.1 second indent MDCG 2019-6 Q IV.6 Q IV.7
Procedures and forms conducted by approprial allocation of tasks and evision Document 1 evision Document 2 Procedures and forms	s to ensure that conformity assessment activities are riately qualified and authorised personnel, and that d changes thereto are documented Comment	4.5.1 second indent MDCG 2019-6 Q IV.6 Q IV.7
Procedures and forms conducted by approprial allocation of tasks and evision Document 1	s to ensure that conformity assessment activities are riately qualified and authorised personnel, and that d changes thereto are documented Comment Comment	4.5.1 second indent MDCG 2019-6 Q IV.6 Q IV.7 MDCG 2021-14
Procedures and forms conducted by approprial allocation of tasks and evision Document 1 evision Document 2 Procedures and forms	s to ensure that conformity assessment activities are riately qualified and authorised personnel, and that d changes thereto are documented Comment Comment	4.5.1 second indent MDCG 2019-6 Q IV.6 Q IV.7 MDCG 2021-14
Procedures and forms conducted by approprial allocation of tasks and evision Document 1 evision Document 2 Procedures and forms	s to ensure that conformity assessment activities are riately qualified and authorised personnel, and that d changes thereto are documented Comment Comment	4.5.1 second indent MDCG 2019-6 Q IV.6 Q IV.7 MDCG 2021-14
	vision Document 1 vision Document 2 tion review and control Template application vision Document 1 vision Document 2 Template contract inconformity assessme the contract template vision Document 1 vision Document 1 vision Document 2 Procedures relating to outcome of each reviewithdrawals of application	tion review and contract Template application form Vision Document 1

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4.5 Conformity assessment activities					
4.5.1 first indent	Procedures for planning the conduct of each individual project				
	evision Document 1	Commont			
	evision Document 1	Comment Comment			
4.5.1 second indent Annex VII		tation of the members of the assessment team at	Annex IX 3.6		
	evision Document 1	Comment	•		
Title and Re	evision Document 2	Comment			
4.5.1 third indent Annex VII	Procedures specifying assessment	g the rationale for fixing time limits for completion of the o	conformity		
Title and Re	evision Document 1	Comment			
Title and Re	evision Document 2	Comment			
4.5.1 Fourth and fifth indents Annex VII	documentation includ	ssessment of the manufacturer's technical ing review of manufacturer's procedures and g to performance evaluation	Annex VII 4.5.3 4.5.4		
Title and Re	evision Document 1	Comment			
	evision Document 2	Comment			
4.5.1 sixth indent Annex VII		sessment of the interface between the manufacturer's rist and its appraisal and analysis of the performance evaluates			
Title and Re	evision Document 1	Comment			
Title and Re	evision Document 2	Comment			
4.5.1 seventh indent Annex VII	Procedures to carry of	out the specific procedures referred to in Sections 5 of Ar	nnex IX		
	evision Document 1	Comment			
4.5.1 eighth indent Annex VII		comment or class C devices, procedures to assess the ion of devices selected on a representative basis	Article 48 Annex VII 4.5.2 Annex IX 2.3 3.5 MDCG 2019-13		
	evision Document 1	Comment			
Title and Re	evision Document 2	Comment			

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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				
Title and Re	vision	Document 1	Comment		
Title and Re	vision	Document 2	Comment		
4.5.1 eleventh	Proce	edures to evalua	te and verify a manufacturer's compliance with relevant	Annexes	
indent Annex VII					
Title and Re	vision	Document 1	Comment		
Title and Re	vision	Document 2	Comment		
4.5.1 Last			to consideration available CS, guidance and best and harmonised standards	MDCG 2019-6	
paragraph Annex VII				Q IV.11	
		Document 1	Comment		
Title and Re	vision	Document 2	Comment		
4.5.2 Quality	y man	agement syste	em auditing		
4.5.2 Annex VII	to ead	edures for the assessment of quality management systems, according ch specific conformity assessment activity covered by the application the class of the device, including:		Annex IX Chapter I	
		wing-up audit pr		MDCG 2019-6	
		•	manufacturing sites, suppliers and/or subcontractors	Q IV.2	
	- Drav	wing-up audit pla	ans		
		wing-up samplin	g plans for classes B and C	MDCG 2019-13	
	OCIC	olion of site auc	anto i S	MDCG 2022-17	
Title and Re	vision	Document 1	Comment		
Title and Re	vision	Document 2	Comment		
4.5.3. Produ	ıct ve	rification			
4.5.3		Procedures to including:	assess the manufacturer's technical documentation,	Article 48	
Assessment				Annex II	
the technical		- Allocations of	personnel	Annex III	
documentati	on	- Conformity of the design			
Annex VII		·	of the implementation by manufacturers of incoming,	Annex IX Chapter II	
		<u> </u>	boratory tests, if required		
		Document 1	Comment	-	
Title and Re	vision	Document 2	Comment		

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4.5.3 Type- examination	documentation		examine and assess the manufacturer's technical and verify the type, including establishment of tests	Annex X	
Annex VII					
Title and Re	evision	Document 1	Comment		
Title and Re	evision	Document 2	Comment	1	
4.5.3 Verification examination	and		relating to verification by examination and testing of patch, including establishment of test plans	Annex IX Annex XI	
testing of exproduct bate					
Annex VII					
		Document 1	Comment		
ritie and Re	evision	Document 2	Comment		
4.5.4 Perfo	rmanc	e evaluation as	sessment		
4.5.4 Annex VII	docui	mentation relatin	view of the manufacturer's procedures and g to performance evaluation, including the validation fety and performance (for class C and D) and the	Article 29 Article 56	
		oad of the summary to EUDAMED			
				6.1; 6.2	
				Annex XIII	
				MDCG 2022-2	
				MDCG 2022-9	
		Document 1	Comment		
Title and Re	evision	Document 2	Comment		
4.5.5 Speci	fic Pro	ocedures			
4.5.5 Annex VII		mentation relatir	ng to documented procedures, expertise and facilities	Article 50 Annex IX	
OX VII	- Ass IX)	essment of devi	ces for self-testing and near-patient testing (5.1 Annex	Sections 4 and 5	
		 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) 		Annex XI	
				Section 5 MDCG	
- Batch verification fo			r class D devices (4.12 Annex IX and 5.1 Annex XI)	2021-4	
				MDCG 2021-22	
				MDCG 2022-3	
Title and Re	evision	Document 1	Comment		
Title and Re	evision	Document 2	Comment	·	

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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 Documentation decision Title and Revision Docume		ng to the final review process carried out prior to making	a final		
Title and Revision Docume		Comment			
4.8 Decisions and Certific					
4.8 <u>Documentation</u>	n relati	ng to the final decision process, including:	Articles 51		
Annex VII - Procedures and withdrawa		ision-making for the issuance, suspension, restriction rtificates	and 52(g) Annex XII		
	- Certificate templates intended to be used for the different types of conformity assessments for which the CAB seeks designation				
		utcome of the assessment and the resultant decision and EUDAMED	MDCG 2019-6		
			Q IV.3		
			Q IV.6		
			Q IV.8		
Title and Revision Docume	ent 1	Comment			
Title and Revision Docume	nt 2	Comment			
4.9 Changes and modific	ations				
Appey VII CAB's assess	ment o	ling manufacturers' information obligations and the f changes, including documented procedures and	MDCG 2019-6		
contractual ar	rangen	nents	Q IV.9		
Title and Revision Docume Title and Revision Docume		Comment Comment			

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4.10 Survei	4.10 Surveillance activities and post-certification monitoring					
4.10 Annex VII	Documentation detailing the following:					
Screening		creening of relevant sources of scientific and clinical data and relating to the scope of designation	and post-			
Title and Re	vision Document 1	Comment				
Title and Re	vision Document 2	Comment	_			
Surveillance activities	'-	ation to surveillance activities, in particular to:	Annex IX			
activities		when surveillance activities of manufacturers are to	Sections 3.3 and			
	,	at least an annual basis)	3.4			
	- Conduct unanno	ounced on-site audits	Annex XI			
		he documentation on vigilance, PMS and PMPF	Section 4			
	- Sample and test	t devices and technical documentation	MPOO			
	- Impose specific withdraw it	restrictions on the relevant certificate, or suspend or	MDCG 2019-6			
			Q IV.10			
Title and Re	vision Document 1	Comment				
Title and Re	vision Document 2	Comment				
Vigilance	estimating the imp	view vigilance data which the NB has access under Article pact on issued certificates, including the recording of the ray decisions taken				
	vision Document 1	Comment				
Title and Re	vision Document 2	Comment	T			
PSUR	Documentation re	elating to the review of periodic safety update reports	Article 81			
	vision Document 1	Comment				
Title and Re	vision Document 2	Comment				
Conditions	Procedures relate	ed to conditions for certification				
	vision Document 1	Comment				
Title and Re	vision Document 2	Comment				
4.11 Re-cer	tification					
4.11	Documentation deta	iling the conduct of re-certification reviews and the	MDCG			
Annex VII	renewal of certificate		2019-6			
Annex vii			Q IV.12			
	evision Document 1	Comment				
Title and Re	vision Document 2	Comment				
Article 53	Documentation relat	ing to voluntary changes of a notified body	MDCG 2018-8			
			MDCG 2019-6			
			Q IV.4			
Title and Re	evision Document 1	Comment				
	evision 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 2nd submission 3rd submission application, version and date) (version and date) (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, policie	s and procedures the conformity	assessment body has in place	to safeguard and promote			
the principles of independence, impartiality and objectivity t						
including procedures providing for the identification, investig						
Personnel commitment and written statement	, , , , , , , , , , , , , , , , , , , ,					
Title and Revision Document 2						
1.2.3 -1.2.7 Independence of the notified body, the larger of	rganisation to which it belongs, t	he top-level management and	conformity assessment			
personnel: Documentation on ensuring independence and i			,			
Title and Revision Document 1						
Title and Revision Document 2						
1.2.8 Documentation demonstrating how the conformity ass	sessment body operates with a s	et of consistent, fair and reaso	nable terms and			
conditions, taking into account small and medium size busin		,				
Title and Revision Document 1						
Title and Revision Document 2						
1.2 Confidentiality						
1.3 Confidentiality						
1.3.1 - 1.3.2 Documentation detailing how the conformity as	ssessment body ensures that its	personnel, committees, subsid	iaries, subcontractors, and			

any accepted hady as nessented of cytested hadise seens	at the confidentiality and correct	of the information /including n	romuiotom (rimbto) vybiob
any associated body or personnel of external bodies respec	ct the confidentiality and secrecy	of the information (including p	roprietary rights) which
comes into their possession	1	1	
Personnel commitment and written statement			
Title and Revision Document 2			
1.4 Liability			
1.4.1 - 1.4.2 Documentation on the liability insurance cover	ing conformity assessment activ	ities, including its scope and ov	rerall financial value
Title and Revision Document 1			
Title and Revision Document 2			
1.5 Financial requirements			
1.5 Documentation detailing the conformity assessment bo	dy's financial resources, includin	g its financial capacity and long	g-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 ensu	uring its personnel is involved in	standardisation activities and in	n the work of the notified
body coordination group and how personnel are informed.			
<u> </u>		T -	
Title and Revision Document 1			

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	es to personnel						
Title and Revision Document 1	•						
Title and Revision Document 2							
2.2 iii) Documentation detailing the assessment and decision	n-making processes in accordar	nce with the tasks, responsibilit	ies 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, evalu	ation and, if necessary, adaptat	ion of the conformity assessme	ent procedures				
Title and Revision Document 1							
Title and Revision Document 2							
2.2 v) Procedures for control of documents including verifica	ation that the documents have th	e same content where docume	ents 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							

Annex to Application Form & PAR Template_IVDR January 2025

Title and Revision Document 2				
2.3 Documentation relating to the implementation and				formity assessment body's
organisation, including subsidiaries and subcontractor	s involved in	in conformity assessment a	ctivities	
Title and Revision Document 1				
Title and Revision Document 2				
2.4 Model declaration of commitment of the CAB's pe	rsonnel to c	comply with the procedures		
Title and Revision Document 1				
Title and Revision Document 2	Title and Revision Document 2			
Articles 32.2; 40.2; 40.3 Procedures on the NB's ob	ligation to n	make available and submit i	upon requests all relevant doc	umentation
Title and Revision Document 1				
Title and Revision Document 2				
Articles 40.1; 42.3; 42.5; Procedures for information	to the author	nority responsible for NBs of	f relevant changes and ceasing	g of activities
42.9				
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 fac		rly the technical, scientific and	administrative tasks			
- Permanent availability of personnel and in sufficient numb		(0.4.0)				
- Sufficient internal competence to critically evaluate assess	sments conducted by external ex	pertise (3.4.3)				
Title and Revision Document 1						
Title and Revision Document 2			1			
3.1.2 Documentation detailing the implementation of a system	em for exchange of experience a	ind a continuous training and e	ducation 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 p	orconnol					
- The extent and limits of duties and responsibilities of the p	ersonner					
- 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						
2.2.1 2.2.2 Decumentation detailing						
 3.2.1 – 3.2.2 <u>Documentation detailing:</u> Process to establish and document the qualification criteria 	a (providing a sufficient lovel of	detail for the required qualificat	ion within the cubdivisions			
of the applied-for scope)	a (providing a sufficient level of t	detail for the required qualificat	ion within the subdivisions			
- Process for selection and authorisation of personnel, inclu	ding the required initial and ongo	oing training				
Title and Revision Document 1						
Title and Revision Document 2						
3.2.2 – 3.2.7 - Specific qualification criteria (3.2.2); Qualification	ation criteria per role:					
- Personnel responsible for establishing qualification criteria	and for authorising other person	nnel (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 ar	nd the satisfaction of the qualifi	cation criteria	
Title and Revision Document 1				
Title and Revision Document 2				
3.3.2 i) Matrix detailing the authorisations (including any lim	itations) and responsibilities of the	ne personnel, including employ	ment status (e.g. full-time,	
external, etc.) and location of all internal and external perso	onnel			
Title and Revision Document 1				
Title and Revision Document 2				
3.3.2 ii) Model/template of the record attesting authorisation				
responsibilities for each of the assessment personnel and r				
Representative sample of records (at least one per role/fun		with the qualification criteria for	or the authorisation of the	
personnel member (mock file or blacked out document mig	ht 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			nent 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 s	ubcontracting 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 Documentation detailing:				
-The initial evaluation, on-going monitoring and periodic rev	riew of competence of the interna	al and external personnel, inclu	iding 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 excha 	nge of experience and the contir	nuous training and education p	rogramme	
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 conf		mprising the individual steps t	from pre-application	
activities up to decision-making and surveillance, e.g. flow	vcharts			
Title and Revision Document 1				
Title and Revision Document 2				
4.1 ii) Documentation detailing the internal activities of the	e CAB which shall not be subc	ontracted	<u></u>	
Title and Revision Document 1				
Title and Revision Document 2				
4.2 Notified body quotations and pre-application activ				
4.2 (a) Description of the application procedure by which	manufacturers can obtain cert	ification, including which lang	juages 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	n 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 ac	tivities 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 te	emplate			
Title and Revision Document 1				

Title and Revision Document 2			
4.3 (a)–(e) Procedures relating to review of applications,	including documented outcome	e of each review and notificat	ion 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 ass	sessment activities are conduc	ted by appropriately qualified	and authorised
personnel, and that allocation of tasks and changes there	to are documented		
Title and Revision Document 1			
Title and Revision Document 2			
4.4 ii) Procedures and forms to identify one individual res	ponsible 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 indiv	ridual 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 appropri	ate intervals	
Title and Revision Document 1			
Title and Revision Document 2			
4.5.1 iii) Procedures specifying the rationale for fixing time	e limits for completion of the co	onformity assessment	
Title and Revision Document 1			
Title and Revision Document 2			
4.5.1 iv-v) Procedures for the assessment of the manufact		n including review of manufa	cturer'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 b	etween the manufacturer's ris	k management process and i	ts 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 Ani	nex IX	
Title and Revision Document 1			
Title and Revision Document 2			

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 1 Title and Revision Document 1 Title and Revision Document 2 4.5.2 Procedures to evaluate to take into consideration available CS, guidance and best practice documents and harmonised standards Title and Revision Document 1	4.5.1 viii) In the case of class B or class C devices, proce	dures to assess the technical	documentation of devices sel	lected on a
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	4.5.3 Documentation relating to verification by examination	on and testing of every product	batch, including establishme	ent of test plans
Title and Revision Document 2	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	4.5.4 Procedures for the review of the manufacturer's pro	cedures and documentation re	elating to performance evalua	ation, including the

validation of the summary of safety and performance (class	ss 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	y 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 conformi	ty assessment are documente	ed and relevant templates of r	eports/records
Title and Revision Document 1			
Title and Revision Document 2			
4.7 Final review			
4.7 Documentation relating to the final review process car	ried 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 o	bligations and the CAB's asse	essment of changes, including	g documented
procedures and contractual arrangements			
Title and Revision Document 1			
Title and Revision Document 2			
4.10 Surveillance activities and post-certification mon	itoring		
4.10 Procedures for screening of relevant sources of scie designation	ntific and clinical data and pos	st-market information relating	to the scope of
Title and Revision Document 1			
Title and Revision Document 2			
4.10 Procedures in relation to surveillance activities	1		

Title and Revision Document 1				
Title and Revision Document 2				
4.10 Procedures to review vigilance data which the NB h	as access under Article 87(2)	and estimating the impact on	issued certificates,	
including the recording of the results of the evaluation ar	d any decisions taken			
Title and Revision Document 1				
Title and Revision Document 2				
4.10 Documentation relating to the review of periodic saf	ety 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				