applicable for ☒ MDR ☐ IVDR

NBOG F 2017-5

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]

DETAILS ON THE APPLICATION AND THE REVIEWERS	
Name and (if applicable) identification number of Conformity Assessment Body (CAB)	
Name of Designating Authority (DA)	
Project number(s) of DA	
Application received on date by DA	
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)[2]	
Date(s) of the review	
Date(s) of previous review(s)/report(s) on this	

[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 39 (3) to the MDR 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 NBOG BPG 2017-X.

[2] 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 colours.

application in case the form is used by the DA for intermediate stages of the review	

OUTCOME OF THE REVIEW[3]	
On the basis of the documents received should it be envisaged to conduct an onsite assessment?	☐ Yes ☐ No
If no, specify why not	

REVIEW OF THE APPLICATION

1. GENERAL AND ORGANISATIONAL REQUIREMENTS	
Are the documents provided for this section deemed a sufficient documented evidence to be taken as a basis for the fulfillment of the designation criteria regarding general and organisational requirements?	☐ Yes ☐ Yes, with issues described below to be clarified <u>during</u> the onsite assessment ☐ No, the deficiencies described below have to be clarified <u>before</u> an onsite assessment can be envisaged[4]

List of documents which have been written/revised and provided to the DA <u>after</u> the application		
Title and revision of documents provided for this section	Applicable sub-section of application	Date on which the document has been received
Title and Revision Document 1		*DD.MM.YYYY*
Title and Revision Document 2		*DD.MM.YYYY*
Title and Revision Document 3		*DD.MM.YYYY*
Title and Revision Document 4		*DD.MM.YYYY*

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

[4] 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).

List of comments on single documents[5]	
General documentation	
1.1 Scope of designation requested under the MDR	
Title and revision of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*
1.2 Authorisation to represent the conformity assessment body by the person who has submitted the application on behalf of the body, unless such authorisation follows from the documentation specified in point 1.5.	
Title and revision of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*
1.3 Valid accreditation certificate and the corresponding evaluation report as referred to in Article 38(2) of Regulation (EU) 2017/745	
Title and revision of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*
1.4 Compliance strategy explaining how the requirements set out in Annex VII of Regulation (EU) 2017/745 have been fulfilled, including, in the case of notified bodies designated under Council Directive 90/385/EEC, Council Directive 93/42/EEC, a gap analysis explaining how the alignment to the new requirements of the Regulations has been achieved	
Title and revision of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*

Legal status and organisational structure	
1.5 Documentation detailing the conformity assessment body's legal personality and its status, including information about ownership and the legal or natural persons exercising control over the conformity assessment body	
Title and revision of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*
1.6 Documentation detailing the activities of the organisation to which the conformity assessment body belongs, the organisational structure and governance of that organisation, and its relationship with the conformity assessment body	
Title and revision of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*

[5] Potential nonconformities and questions to be clarified should be detailed as much as possible including the sections of the documents in order to facilitate the understanding. 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.
Issues to be clarified before an on-site assessment can be envisaged are written in bold, other issues are to be clarified during the on-site assessment.

1.7 Documentation detailing the activities and responsibilities of any legal entity which is wholly or partly owned by the conformity assessment body or which wholly or partly owns the conformity assessment body, and the legal and operational relationships with the conformity assessment body	
Title and revision of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*
1.8 Documentation describing the organisational structure, the allocation of responsibilities, reporting lines and the operational management of the conformity assessment body	
Title and revision of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*
1.9 Documentation detailing the functions, responsibilities and authorities of the top-level management, including the individual having overall responsibility for all conformity assessment activities in relation to devices (head of the notified body)	
Title and revision of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*

Independence, impartiality and confidentiality	
1.10 Documentation detailing the structures, policies and procedures the conformity assessment body has in place to safeguard and promote the principles of independence, impartiality and objectivity throughout its organisation, personnel and activities, including procedures providing for the identification, investigation and resolution of any case in which a conflict of interest may arise	
Title and revision of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*
1.11 Documentation detailing how the conformity assessment body ensures that the activities of its owners, its subsidiaries and subcontractors (including external experts), or of any associated body do not affect its independence and impartiality or the objectivity of its conformity assessment activities	
Title and revision of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*
1.12 If the conformity assessment body is owned by a public entity or institution, documentation detailing how independence and absence of any conflict of interest with the authority responsible for notified bodies and/or the competent authority is ensured	
Title and revision of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*
1.13 Documentation detailing involvement of personnel in consultancy services in the field of devices prior to taking up employment with the conformity assessment body and detailing monitoring and resolution of potential conflicts of interest	
Title and revision of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*

1.14 Documentation detailing the conditions governing the remuneration of all employees (including top-level management and contracted staff)	
Title and revision of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*
1.15 Documentation detailing how the conformity assessment body ensures that its personnel, committees, subsidiaries, subcontractors, and any associated body or personnel of external bodies respect the confidentiality of the information (including proprietary rights) which comes into their possession when carrying out their tasks (1.3.1, 1.3.2 and 2.4) and documentation on professional secrecy arrangements	
Title and revision of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*

Liability insurance and financial resources	
1.16 Documentation on the liability insurance covering conformity assessment activities, including its scope and overall financial value	
Title and revision of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*
1.17 Documentation detailing the conformity assessment body's financial resources, including its financial capacity and long-term economic viability	
Title and revision of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*

2. QUALITY MANAGEMENT REQUIREMENTS	
Are the documents provided for this section deemed a sufficient documented evidence to be taken as a basis for the fulfillment of the designation criteria regarding quality management requirements?	☐ Yes ☐ Yes, with issues described below to be clarified <u>during</u> the onsite assessment ☐ No, the deficiencies described below have to be clarified <u>before</u> an onsite assessment can be envisaged[6]

List of documents which have been written/revised and provided to the DA <u>after</u> the application		
Title and revision of documents provided for this section	Applicable sub-section of application	Date on which the document has been received
Title and Revision Document 1		*DD.MM.YYYY*
Title and Revision Document 2		*DD.MM.YYYY*

[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).

Title and Revision Document 3		*DD.MM.YYYY*
Title and Revision Document 4		*DD.MM.YYYY*

List of comments on single documents[7]	
Documentation on the quality management system addressing at least the following	
2.1 management system structure and the list of all quality management system documents, and the sequence and interrelation of processes	
Title and revision of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*
2.2 the quality manual and policies and objectives for the conformity assessment body's activities	
Title and revision of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*
2.3 control of documents including verification that the documents have the same content where documents are used in different languages	
Title and revision of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*
2.4 control of records	
Title and revision of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*
2.5 management reviews	
Title and revision of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*
2.6 internal audits and monitoring of the conformity assessment activities and performance of personnel and subcontractors	
Title and revision of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*
2.7 corrective and preventive actions	
Title and revision of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*

[7] Potential nonconformities and questions to be clarified should be detailed as much as possible including the sections of the documents in order to facilitate the understanding. 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.
Issues to be clarified before an on-site assessment can be envisaged are written in bold, other issues are to be clarified during the on-site assessment.

2.8 complaints and appeals	
Title and revision of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*
2.9 Documentation relating to the implementation and maintenance of the quality management system throughout the conformity assessment body's organisation, including subsidiaries and subcontractors involved in conformity assessment activities	
Title and revision of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*
2.10 Model declaration of commitment of the conformity assessment body's personnel to comply with the procedures defined by the body	
Title and revision of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*

3. RESOURCE REQUIREMENTS	
Are the documents provided for this section deemed a sufficient documented evidence to be taken as a basis for the fulfillment of the designation criteria regarding resource requirements?	☐ Yes ☐ Yes, with issues described below to be clarified <u>during</u> the onsite assessment ☐ No, the deficiencies described below have to be clarified <u>before</u> an onsite assessment can be envisaged[8]

List of documents which have been written/revised and provided to the DA <u>after</u> the application		
Title and revision of documents provided for this section	Applicable sub-section of application	Date on which the document has been received
Title and Revision Document 1		*DD.MM.YYYY*
Title and Revision Document 2		*DD.MM.YYYY*
Title and Revision Document 3		*DD.MM.YYYY*
Title and Revision Document 4		*DD.MM.YYYY*

[8] 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).

List of comments on single documents[9]	
Qualification and authorisation of personnel	
3.1 Matrix based on the established (specific) qualification criteria in accordance with section 3.4 of this document, detailing the authorisations (including any limitations) and responsibilities in respect of conformity assessment activities, and functions, fields of competence, employment status (e.g. full-time, external, etc.) and location of all internal and external personnel referred to in Sections 3.2.4-3.2.7 of Annex VII of Regulation (EU) 2017/745; the authorisations and responsibilities in respect of conformity assessment activities shall be specified by using the codes set out in the Commission Implementing Regulation on codes and corresponding types of devices, see NBOG F-2017-3	
Title and revision of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*
3.2 List of any additional personnel (other than referred to in 3.1) supporting conformity assessment activities, detailing the duties, responsibilities and level of authorisation (job descriptions), employment status (e.g. full-time, external, etc.) and location of each individual	
Title and revision of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*
3.3 Templates of employment and other contracts used for the conformity assessment body's personnel	
Title and revision of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*
3.4 Documentation detailing the established (specific) qualification criteria for each function within the conformity assessment process, as well as the types of devices, technologies and areas within the subdivisions of the scope of designation applied for. The qualification criteria shall be specified at least for each of the following roles and function categories: personnel responsible for establishing qualification criteria and authorising personnel to conformity assessment activities, personnel with relevant clinical expertise, product reviewer, site auditor, personnel with overall responsibility for final reviews and decision-making on certification	
Title and revision of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*
3.5 Documentation relating to the procedures for the selection and authorisation of persons involved in conformity assessment activities, including the procedures to document the qualification of each person and the satisfaction of the qualification criteria	
Title and revision of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*

9 Potential nonconformities and questions to be clarified should be detailed as much as possible including the sections of the documents in order to facilitate the understanding. 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.
Issues to be clarified before an on-site assessment can be envisaged are written in bold, other issues are to be clarified during the on-site assessment.

3.6 Representative sample of records (at least one per function) demonstrating compliance with the qualification criteria for the authorisation of the personnel member	
Title and revision of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*

Monitoring, training, exchange of experience	
3.7 Documentation detailing the initial evaluation, on-going monitoring and periodic review of competence of the internal and external personnel, including the identification of training needs and drawing up of training plans	
Title and revision of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*
3.8 Documentation detailing a continuous training and education programme	
Title and revision of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*
3.9 Documentation detailing the implementation of a system for exchange of experience	
Title and revision of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*
3.10 Documentation detailing how the personnel is informed of any relevant standardisation activities, legislation, guidance, and the activities of the notified body coordination group referred to in Article 49 of Regulation (EU) 2017/745	
Title and revision of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*

Equipment and facilities	
3.11 List of all tests that the conformity assessment body will be able to perform and of the relevant equipment and facilities, including testing facilities, in possession of the conformity assessment body and which are to be used in its conformity assessment activities	
Title and revision of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*

Subcontractors	
3.12 Lists of all subcontractors and subsidiaries as referred to in Article 37 of Regulation (EU) 2017/745, 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 of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*

3.13 Documentation detailing the procedures for selecting, evaluating and monitoring the competence of subcontractors involved in conformity assessment activities	
Title and revision of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*
3.14 Documentation detailing the conditions under which subcontracting may take place	
Title and revision of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*
3.15 Documentation demonstrating internal competence in each product area for the conformity assessment activities for which subcontractors or external experts are used	
Title and revision of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*

4. PROCESS REQUIREMENTS			
Are the documents provided for this section deemed a sufficient documented evidence to be taken as a basis for the fulfillment of the designation criteria regarding process requirements?	☐ Yes ☐ Yes, with issues described below to be clarified <u>during</u> the onsite assessment ☐ No, the deficiencies described below have to be clarified <u>before</u> an onsite assessment can be envisaged[10]		
List of documents which have been written/revised and provided to the DA <u>after</u> the application			
Title and revision of documents provided for this section		Applicable sub-section of application	Date on which the document has been received
Title and Revision Document 1			*DD.MM.YYYY*
Title and Revision Document 2			*DD.MM.YYYY*
Title and Revision Document 3			*DD.MM.YYYY*
Title and Revision Document 4			*DD.MM.YYYY*

[10] 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).

List of comments on single documents[11]	
Quotations, pre-application activities, application review and contract	
Documentation relating to procedures for quotations and pre-application activities, including	
4.1 description of the application procedure by which manufacturers can obtain certification	
Title and revision of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*
4.2 fees charged and financial conditions	
Title and revision of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*
4.3 advertising of conformity assessment services	
Title and revision of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*
4.4 review of pre-application information	
Title and revision of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*
Documentation relating to contractual arrangements between the manufacturer and the conformity assessment body, including	
4.5 template application form	
Title and revision of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*
4.6 template contract specifying terms and conditions and obligations of the conformity assessment body in relation to conformity assessment activities	
Title and revision of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*
4.7 Procedures relating to review of applications	
Title and revision of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*

[11] Potential nonconformities and questions to be clarified should be detailed as much as possible including the sections of the documents in order to facilitate the understanding. 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.
Issues to be clarified before an on-site assessment can be envisaged are written in bold, other issues are to be clarified during the on-site assessment.

4.8 Procedures to ensure that all contracts relating to the conformity assessment activities are concluded directly between the manufacturer and the conformity assessment body	
Title and revision of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*

Allocation of resources	
4.9 Procedures and forms to ensure that conformity assessment activities are conducted by appropriately qualified and authorised personnel, including the identification of one individual responsible for each application, and that allocation of tasks and changes thereto are documented	
Title and revision of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*
Documentation relating to project planning, including	
4.10 planning the conduct of each individual project and specifying the rationale for fixing time limits for completion of the conformity assessment	
Title and revision of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*
4.11 rotation of the members of the assessment team at appropriate intervals	
Title and revision of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*

Conformity assessment activities	
4.12 Documentation relating to the assessment of manufacturers' technical documentation, including:	
Title and revision of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*
4.13the review of the manufacturer's procedures and documentation relating to the evaluation of pre-clinical aspects of medical devices	
Title and revision of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*
4.14 the review of the manufacturer's procedures and documentation relating to clinical evaluation of medical devices	
Title and revision of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*

4.15 the assessment of the interface between the manufacturer's risk management process and its appraisal and analysis of the pre-clinical and clinical evaluation	
Title and revision of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*
4.16 assessments of technical documentations for class IIa and class IIb medical devices selected on a representative basis and according to a sampling plan	
Title and revision of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*
4.17 validation of the summary of safety and clinical performance, in accordance with Article 32 of Regulation (EU) 2017/745	
Title and revision of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*
4.18 Documentation relating to quality management system audits according to each specific conformity assessment activity covered by the application and the class of the device	
Title and revision of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*
4.19 Documentation relating to type-examination, including establishment of test plans	
Title and revision of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*
4.20 Documentation relating to verification by examination and testing of every product, including establishment of test plans	
Title and revision of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*
4.21 Documentation relating to carrying out the specific procedures referred to in Sections 5 and 6 of Annex IX, Section 6 of Annex X and Section 16 of Annex XI to Regulation (EU) 2017/745	
Title and revision of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*

Final review and decision making on certification	
4.22 Documentation relating to the final review process carried out prior to making a final decision	
Title and revision of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*

4.23 Documentation relating to the final decision process prior to the issuance, suspension, restriction or withdrawal of a certificate and the communication to the manufacturer	
Title and revision of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*
4.24 Certificate templates intended to be used for the different types of conformity assessments for which the conformity assessment body seeks designation, in accordance with Annex XII of Regulation (EU) 2017/745	
Title and revision of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*

Post-certification activities	
4.25 Documentation detailing the information obligations and communications with the electronic system referred to in Article 57 of Regulation (EU) 2017/745	
Title and revision of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*
4.26 Documentation relating to the review of periodic safety update reports referred to in Article 86 of Regulation (EU) 2017/745	
Title and revision of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*
4.27 Documentation relating to surveillance and post-certification monitoring, including:	
Title and revision of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*
4.28 screening of relevant sources of scientific and clinical data and post-market information relating to the scope of designation	
Title and revision of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*
4.29 review, documentation and management of vigilance information	
Title and revision of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*
4.30 estimation of the impact of vigilance information on the validity of existing certificates	
Title and revision of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*

4.31 taking any appropriate actions	
Title and revision of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*
4.32 surveillance audits	
Title and revision of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*
4.33 unannounced audits	
Title and revision of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*
4.34 Documentation relating to sampling of devices	
Title and revision of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*
4.35 Documentation detailing manufacturers' information obligations and the conformity assessment body's assessment of changes	
Title and revision of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*
4.36 Documentation detailing the conduct of re-certification reviews and the renewal of certificates	
Title and revision of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*
4.37 Documentation relating to voluntary changes of a notified body in accordance with Article 58 of Regulation (EU) 2017/745	
Title and revision of document	Comment
Title and Revision Document 1	*Comment*
Title and Revision Document 2	*Comment*