Draft list of documents to be submitted in the application for designation as a notified body under Regulation (EU) 2017/745 and Regulation (EU) 2017/746

This draft list of documents has been created in the context of preparations of the future implementing act under Articles 39(10) MDR and 35(10) IVDR. The document has not been adopted or endorsed by the European Commission, and any views expressed reflect the preliminary discussions of the Commission services and Member States' authorities, and they may not be regarded as stating an official position of the Commission.

The document is intended for information about the preparatory works on the future implementing legislation and it is without prejudice to the final text of such implementing legislation.

Any draft implementing legislation will be made available for public feedback in due time, through the feedback mechanism at the following website:

https://ec.europa.eu/info/law/better-regulation/have-your-say_en

1. GENERAL AND ORGANISATIONAL REQUIREMENTS

(a) specification of the conformity assessment activities and types of devices to be covered by the designation using the codes set out in Implementing Regulation *[…]*;

(b) 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 (e);

(c) when available, a valid accreditation certificate and the corresponding evaluation report as referred to in Article 38(2) of Regulation (EU) 2017/745 and Article 34(2) of Regulation (EU) 2017/746;

(d) compliance strategy explaining how the requirements set out in Annex VII of Regulation (EU) 2017/745 or Annex VII of Regulation (EU) 2017/746 have been fulfilled, including, in the case of notified bodies designated under Council Directive 90/385/EEC[1], Council Directive 93/42/EEC[2] or Directive of the European Parliament and the Council 98/79/EC[3], a gap analysis explaining how the alignment to the new requirements of the Regulations has been achieved;

1 Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (OJ L 189, 20.7.1990, p. 17).

2 Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1).

3 Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices OJ L 331, 7.12.1998, p. 1).

(e) documentation detailing the conformity assessment body's legal personality and its status, including information about ownership and the legal or natural persons exercising control over the conformity assessment body (1.1.1)[4];

(f) documentation detailing the activities of the organisation to which the conformity assessment body belongs, the organisational structure and governance of that organisation, and its relationship with the conformity assessment body (1.1.2);

(g) 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 (1.1.3);

(h) documentation describing the organisational structure, the allocation of responsibilities, reporting lines and the operational management of the conformity assessment body (1.1.4);

(i) documentation detailing the functions, responsibilities and authorities of the top-level management, including the individual having overall responsibility for all conformity assessment activities in relation to devices (head of the notified body) (1.1.5, 1.1.6 and 3.1.1);

(j) documentation detailing the structures, policies and procedures the conformity assessment body has in place to safeguard and promote the principles of independence, impartiality and objectivity throughout its organisation, personnel and activities, including procedures providing for the identification, investigation and resolution of any case in which a conflict of interest may arise (1.2.1, 1.2.2, 1.2.3, 1.2.7, 2.4, 4.5.1 and 4.5.3);

(k) documentation detailing how the conformity assessment body ensures that the activities of its owners, its subsidiaries and subcontractors (including external experts), or of any associated body do not affect its independence and impartiality or the objectivity of its conformity assessment activities (1.2.7, 2.4 and 3.4.2);

(l) if the conformity assessment body is owned by a public entity or institution, documentation detailing how independence and absence of any conflict of interest with the authority responsible for notified bodies and/or the competent authority is ensured (1.2.6);

(m) documentation detailing involvement of personnel in consultancy services in the field of devices prior to taking up employment with the conformity assessment body and detailing monitoring and resolution of potential conflicts of interest (1.2.4);

(n) documentation detailing the conditions governing the remuneration of all employees (including top-level management and contracted staff) (1.2.5);

(o) 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, 2.4 and 3.4.2), and documentation on professional secrecy arrangements (1.3.2);

(p) documentation on the liability insurance covering conformity assessment activities, including its scope and overall financial value (1.4);

4 Numbers in brackets refer to the relevant sections of Annex VII to Regulation (EU) 2017/745 and Annex VII to Regulation (EU) 2017/746, as appropriate.

(q) documentation detailing the conformity assessment body's financial resources, including its financial capacity and long-term economic viability (1.5).

2. QUALITY MANAGEMENT REQUIREMENTS

(a) documentation on the quality management system addressing at least the following:

(i) management system structure and the list of all quality management system documents, and the sequence and interrelation of processes (2.2);

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

(iii) control of documents including verification that the documents have the same content where documents are used in different languages (2.2);

(iv) control of records (2.2);

(v) management reviews (2.2);

(vi) internal audits (2.2) and monitoring of the conformity assessment activities and performance of personnel and subcontractors (3.5.1);

(vii) corrective and preventive actions (2.2);

(viii) complaints and appeals (2.2);

(b) documentation relating to the implementation and maintenance of the quality management system throughout the conformity assessment body's organisation, including subsidiaries and subcontractors involved in conformity assessment activities (2.3);

(c) model declaration of commitment of the conformity assessment body's personnel to comply with the procedures defined by the body (2.4).

3. RESOURCE REQUIREMENTS

(a) matrix based on the established (specific) qualification criteria in accordance with paragraph (d), 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 3.2.3-3.2.7 of Annex VII of Regulation (EU) 2017/745 and/or Sections 3.2.3-3.2.7 of Annex VII of Regulation (EU) 2017/746; the authorisations and responsibilities in respect of conformity assessment activities shall be specified by using the codes set out in Implementing Regulation *[…]* (3.3.2);

(b) list of any additional personnel other than referred to in paragraph (a) supporting conformity assessment activities, detailing the duties, responsibilities and level of authorisation (job descriptions), employment status (e.g. full-time, external, etc.) and location of each individual (3.1.1, 3.1.3 and 3.4.1);

(c) templates of employment and other contracts used for the conformity assessment body's personnel;

(d) documentation detailing the established (specific) qualification criteria for each function within the conformity assessment process, as well as the types of devices, technologies and areas within the subdivisions of the scope of

designation applied for (3.2); the qualification criteria shall be specified at least for each of the following roles and function categories: personnel responsible for establishing qualification criteria and authorising personnel to conformity assessment activities (3.2.3); personnel with the relevant clinical expertise (3.2.4); product reviewer (3.2.5); site auditor (3.2.6); personnel with overall responsibility for final reviews and decision-making on certification (3.2.7);

(e) documentation relating to the procedures for the selection and authorisation of persons involved in conformity assessment activities, including the procedures to document the qualification of each person and the satisfaction of the qualification criteria (3.2.1, 3.3.1);

(f) representative sample of records (at least one per function) demonstrating compliance with the qualification criteria for the authorisation of the personnel member (3.3.2);

(g) documentation detailing the initial evaluation, on-going monitoring and periodic review of competence of the internal and external personnel, including the identification of training needs and drawing up of training plans (3.5.1 and 3.5.2);

(h) documentation detailing a continuous training and education programme (2.2, 3.1.2);

(i) documentation detailing the implementation of a system for exchange of experience (3.1.2);

(j) 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 and/or Article 45 of Regulation (EU) 2017/746 (1.6.1 and 3.5.2);

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

(l) lists of all subcontractors and subsidiaries as referred to in Article 37 of Regulation (EU) 2017/745 and/or Article 33 of Regulation (EU) 2017/746, including a description of their functions in relation to conformity assessment activities (e.g. external laboratories) or administrative tasks (e.g. information technologies) and contractual arrangements in place (3.1.1 and 3.4.1);

(m) documentation relating to procedures for selecting, evaluating and monitoring the competence of subcontractors involved in conformity assessment activities (3.5.1);

(n) documentation detailing the conditions under which subcontracting may take place (3.4.2);

(o) documentation demonstrating internal competence in each product area for the conformity assessment activities for which subcontractors or external experts are used (3.4.3).

4. PROCESS REQUIREMENTS

(a) documentation relating to procedures for quotations and pre-application activities, including:

(i) description of the application procedure by which manufacturers can obtain certification (4.2(a));

(ii) fees charged and financial conditions (4.2(b));

(iii) advertising of conformity assessment services (4.2(c));

(iv) review of pre-application information (4.2(d));

(b) documentation relating to contractual arrangements between the manufacturer and the conformity assessment body, including:

(i) template application form (4.3);

(ii) template contract specifying terms and conditions and obligations of the conformity assessment body in relation to conformity assessment activities (4.3);

(iii) procedures relating to review of applications (4.3):

– the verification of completeness of the application;

– the verification of the qualification and classification of the product;

– the applicability of the conformity assessment procedures chosen by the applicant;

– the ability of the conformity assessment body to assess the application in accordance with the scope of designation applied for;

– the availability of sufficient and appropriate resources;

(iv) procedures to ensure that all contracts relating to the conformity assessment activities are concluded directly between the manufacturer and the conformity assessment body (4(2)(e));

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

(d) documentation relating to project planning (4.5.1), including:

(i) planning the conduct of each individual project and specifying the rationale for fixing time limits for completion of the conformity assessment;

(ii) rotation of the members of the assessment team at appropriate intervals;

(e) documentation relating to the assessment of manufacturers' technical documentation (4.5.1 and 4.5.3), including:

(i) the review of the manufacturer's procedures and documentation relating to the evaluation of pre-clinical aspects of medical devices (4.5.1 and 4.5.4);

(ii) the review of the manufacturer's procedures and documentation relating to clinical evaluation of medical devices and/or performance evaluation of in vitro diagnostic medical devices (4.5.1 and 4.5.5);

(iii) the assessment of the interface between the manufacturer's risk management process and its appraisal (4.5.1);

(iv) assessments of technical documentations for class IIa and class IIb medical devices and/or class B and class C *in vitro* diagnostic

medical devices selected on a representative basis and according to a sampling plan (4.5.1, 4.5.2(a) and 4.10);

(v) validation of the summary of safety and clinical performance, in accordance with Article 32 of Regulation (EU) 2017/745 and/or summary of safety and performance in accordance with Article 29 of Regulation (EU) 2017/746;

(f) documentation relating to quality management system audits according to each specific conformity assessment activity covered by the application and the class of the device (4.5.2);

(g) documentation relating to type-examination, including establishment of test plans (4.5.3);

(h) documentation relating to verification by examination and testing of every product, including establishment of test plans (4.5.3);

(i) 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 and/or Section 5 of Annex IX to Regulation (EU) 2017/746 (4.5.1 and, as appropriate, for Regulation (EU) 2017/745 - 4.5.6, and - for Regulation (EU) 2017/746 - 4.5.5);

(j) documentation relating to the final review process carried out prior to making a final decision (4.7);

(k) documentation relating to the final decision process prior to the issuance, suspension, restriction or withdrawal of a certificate and the communication to the manufacturer (4.8);

(l) 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 and/or Annex XII of Regulation (EU) 2017/746 (4.8);

(m) documentation detailing the information obligations and communications with the electronic system referred to in Article 57 of Regulation (EU) 2017/745 and/or Article 52 of Regulation (EU) 2017/746 (4.8);

(n) documentation relating to the review of periodic safety update reports referred to in Article 86 of Regulation (EU) 2017/745 and/or Article 81 of Regulation (EU) 2017/746;

(o) documentation relating to surveillance and post-certification monitoring (4.10), including:

(i) screening of relevant sources of scientific and clinical data and post-market information relating to the scope of designation;

(ii) review, documentation and management of vigilance information;

(iii) estimation of the impact of vigilance information on the validity of existing certificates;

(iv) taking any appropriate actions;

(v) surveillance audits (4.5.1 and 4.10);

(vi) unannounced audits (4.5.1 and 4.10);

(p) documentation relating to sampling of devices (4.5.1);

(q) for applications under Regulation (EU) 2017/746, documentation relating to batch release (3.2.1);

(r) documentation detailing manufacturers' information obligations and the conformity assessment body's assessment of changes (4.9);

(s) documentation detailing the conduct of re-certification reviews and the renewal of certificates (4.11);

(t) documentation relating to voluntary changes of a notified body in accordance with Article 58 of Regulation (EU) 2017/745 and/or Article 53 of Regulation (EU) 2017/746.

5. The conformity assessment body which has not been designated as a notified body under Regulation (EU) 2017/745 or, as appropriate, Regulation (EU) 2017/746 shall make available to the designating authority and the joint assessment team, at the beginning of the on-site assessment, at least one mock up for each conformity assessment activity to be covered by the designation, including technical documentation and the assessment thereof.