ANNEX II

Application form to be submitted when applying for designation as notified body

Designating authority: …

Name of the applying conformity assessment body: …

Previous name (if applicable): …

EU Notified Body number (if applicable): …

Address: …

…

…

…

Contact person: …

E-mail: …

Telephone: …

Legal form of the conformity assessment body: …

Company registration number: …

At company register: …

…

…

The following documents shall be added. In case of extension or renewal, only new or modified documents shall be submitted.

Item/issue		**Corresponding Annex I section**	**Attachment number + Reference(Section/ page)**
ORGANISATIONAL AND GENERAL REQUIREMENTS			
Legal status and organisational structure			
1	Company statutes		
2	Extract of company registration or enrolment act (Company register)		
3	Documentation on the activities of the organisation to which the conformity assessment body belongs (if any) and its relationship		

	with the conformity assessment body		
4	Documentation on entities the conformity assessment body owns (if any), either within the Member State or outside, and the relationship with those entities		
5	Description of legal ownership and the legal or natural persons exercising control of the conformity assessment body		
6	Description of organisational structure and the operational management of the conformity assessment body		
7	Descriptions of functions, responsibilities and authorities of top-level management		
8	List of all staff who have an influence in the conformity assessment activities		
9	Documentation on other services provided by the conformity assessment body (if any) (e.g. consultancy relevant to devices, training etc.)		
10	Documentation on accreditation(s) relevant to this application		
Independence and impartiality			

11	Documentation on structures, policies and procedures to safeguard and promote the principles of impartiality throughout the organisation, personnel and assessment activities, including ethical rules or codes of conduct		
12	Description of how the conformity assessment body ensures that the activities of subsidiaries, subcontractors and external experts do not affect its independence, impartiality or objectivity		
13	Documentation on the impartiality of the top-level management and personnel involved in conformity assessment activities, including their remuneration and bonuses		
14	Documentation on conflict of interest and resolution of potential conflict procedure/form		
15	Description of independence of the conformity assessment body from the designating authority and from the competent authority, in particular when this		

	body is a public entity/institution		
Confidentiality			
16	Documentation on professional secrecy procedure including protection of proprietary data		
Liability			
17	Documentation of the liability insurance, proof that the liability insurance covers cases where the notified body may be obliged to withdraw or suspend certificates		
Financial resources			
18	Documentation of the financial resources required to conduct the conformity assessment activities, related operations, including the ongoing commitments for certificates issued to demonstrate the continuing viability of the notified body and consistency with the range of products certified		
Quality system			
19	Quality Manual and a list of related documentation on the implementation, maintenance and operation of a quality management system, including policies for assignment of personnel to activities and their responsibilities		

20	Documentation on the procedure(s) for control of documents		
21	Documentation on the procedure(s) for control of records		
22	Documentation on the procedure(s) for management review		
23	Documentation on the procedure(s) for internal audits		
24	Documentation on the procedure(s) for corrective and preventive actions		
25	Documentation on the procedure(s) for complaints and appeals		
Resource requirements			
General			
26	Description of own laboratories and testing facilities		
27	Employment contracts and other agreements with internal personnel, in particular in relation to impartiality, independence, conflict of interest (attach a standard contract template)		
28	Contracts and other agreements with subcontractors and external experts, in particular for impartiality, independence, conflict of interest (attach a standard contract template)		
Qualification and authorisation of personnel			

29	List of all permanent and temporary personnel (technical, administrative etc.) including information on professional qualification, past experience and the types of contracts held		
30	List of all external personnel (e.g. external experts, external auditors) including information on professional qualification, past experience and on the types of contracts held		
31	Qualification matrix linking the body's staff and its external experts to the functions to be accomplished by them and to the fields of competence for which the body has been notified or wishes to be notified		
32	Qualification criteria for the different functions (see point 31)		
33	Documentation on the procedure(s) for selection and assignment of internal or external personnel involved in the conformity assessment activities, including conditions for the attribution of tasks to external personnel and the supervision of their expertise		

34	Documentation demonstrating that the management of the conformity assessment body has appropriate knowledge to set up and operate a system for: — the selection of the personnel deployed during the conformity assessment, — the verification of the knowledge and experience of this personnel, — the assignment of the personnel to their tasks, — the verification of the performance of the personnel, — the definition and the verification of their initial and ongoing training		
35	Documentation on the procedure assuring ongoing monitoring of competences and performance monitoring		

36	Documentation on standard training programmes conducted by the conformity assessment body relevant to the conformity assessment activities		
Subcontractors			
37	List of all subcontractors (not individual external experts) used for conformity assessment activities		
38	Subcontractor policy and procedure		
39	Documentation demonstrating adequate core competence within the conformity assessment body to assess, select, contract, and to verify the appropriateness and validity of subcontractor activities		
40	Examples of standard template contract, prohibiting further subcontracting by legal persons and specifically including provisions to ensure confidentiality and conflict of interest management with subcontractors (attach examples)		
Process			
41	Documentation on procedures relating to conformity assessment activities and other related documents reflecting the scope		

of conformity assessment activities including, in particular procedures relating to: — Qualification and classification — Quality system assessments — Risk management — Pre-clinical data evaluation — Clinical evaluation — Representative sampling of technical documentation — Post-market clinical follow up — Communications from regulatory authorities including competent authorities and designating authorities — Communication and analysis of the impact of vigilance reports on device certification — Consultation procedures for drug-device combination products, devices utilising animal tissue,		

	devices utilising human blood derivatives — Review and decision making on certificate issuance including approval responsibilities — Review and decision making on certificate suspension, restriction, withdrawal and refusal including approval responsibilities		
42	Checklists, templates, reports and certificates used for the conformity assessment activities		

Name and signature of an authorised representative of the applicant conformity assessment body (unless electronic signature is accepted)		Place and date

Status:
Point in time view as at 31/12/2020.

Changes to legislation:
Commission Implementing Regulation (EU) No 920/2013, ANNEX II is up to date with all changes known to be in force on or before 22 March 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations.