ANNEX II

Application form to be submitted when applying for designation as [F1an approved] body

Textual Amendments

F1 Words in Annex 2 heading substituted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 32(a)**

Designating authority: …

Name of the applying conformity assessment body: …

Previous name (if applicable): …

[F2Approved**]** Body number (if applicable): …

Textual Amendments

F2 Word in Annex 2 substituted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 32(b)**

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) **F3** ...		
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 **[**F4the Secretary of State**]**		
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 **[**F5approved 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 **[**F5approved 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 **[**[F6]approved**]** or wishes to be **[**[F6]approved**]**		
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 — **[**[F7]Communications from the Secretary of State or other regulatory 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		

Textual Amendments

F3 Words in Annex 2 omitted (11.8.2021) by virtue of The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 32(c)(i)**

F4 Words in Annex 2 substituted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 32(c)(ii)**

F5 Words in Annex 2 substituted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 32(c)(iii)**

F6 Word in Annex 2 substituted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 32(c)(iv)**

F7 Words in Annex 2 substituted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 32(c)(v)**

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

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 10 January 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.
View outstanding changes

Changes and effects yet to be applied to :

– Regulation revoked by S.I. 2002/618, reg. 4L(1)(2) (as inserted) by S.I. 2019/791 reg. 3(7)